

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

Reference: 92440695-FA

21 October 2019

Urgent Field Safety Notice - Urgent Medical Device Recall Advanix™ Pancreatic Stents

Dear «Users_Name»,

Boston Scientific is initiating a voluntary removal of certain Advanix™ Pancreatic Stents because the “Use by Date” displayed on the labels of affected products is incorrect and is later than the actual “Use by Date”. Some devices in distribution have surpassed the correct “Use by Date”. While the “Use by Date” is incorrect, there are no adverse health consequences expected to occur. Boston Scientific has data to support both that the Advanix Stent performs as intended and that the packaging maintains the sterile barrier of the device through a 36-month timeframe, if used by the incorrect “Use by Date”. Due to this the affected Advanix Pancreatic Stents that have been implanted do not require special follow-up or monitoring.

This removal does not include stents packaged as part of the NaviFlex™ RX Delivery System.

Our records indicate that your facility received some of the concerned product.

The **Attachment 1 below provides a complete list of all affected products**, including Product Description, Material Number (UPN), Batch numbers, GTIN, and expiration 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 affected product should cease immediately.

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 **8 November 2019**.

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

Attachment 1 : Affected Product Listing

This is a list of all products in scope. Please refer to your individual Reply Verification Tracking Form for the specific UPN and Batches that were shipped to your facility.

Product Description	Material Number (UPN)	GTIN	Batch	Expiration Date
Advanix™ Pancreatic Stents	M00536610	8714729857556	21312746	27-Oct-20
			21776485	21-Feb-21
			22737577	1-Oct-21
			23257631	27-Jan-22
			24271827	14-Aug-22
	M00536620	8714729857563	21776487	21-Feb-21
			22136470	17-May-21
			22896244	5-Nov-21
			23902871	4-Jun-22
	M00536630	8714729857570	21483840	6-Dec-20
			21512594	13-Dec-20
			21724125	8-Feb-21
			21833851	7-Mar-21
			22007180	17-Apr-21
			22195528	31-May-21
			22212528	5-Jun-21
			22647190	12-Sep-21
			22828072	21-Oct-21
			23000367	27-Nov-21
			23257632	27-Jan-22
			23578453	1-Apr-22
			23615959	8-Apr-22
			23796006	14-May-22
			24167478	24-Jul-22
			24229865	6-Aug-22
			24396823	8-Sep-22
	M00536640	8714729857587	21973220	9-Apr-21
			22522254	15-Aug-21
			23837823	21-May-22
	M00536650	8714729857594	21187998	27-Sep-20
			21285271	20-Oct-20
			21337147	2-Nov-20
			21483841	6-Dec-20
			21512595	13-Dec-20
			21662812	25-Jan-21
			21724126	8-Feb-21
			21833852	7-Mar-21
			21922988	27-Mar-21
			22036149	24-Apr-21
			22136471	17-May-21
	22307745	26-Jun-21		

Product Description	Material Number (UPN)	GTIN	Batch	Expiration Date
Advanix™ Pancreatic Stents	M00536650 (Continued)	8714729857594	22359735	10-Jul-21
			22613955	5-Sep-21
			22700891	24-Sep-21
			23035017	4-Dec-21
			23295961	4-Feb-22
			23492660	14-Mar-22
			23541961	25-Mar-22
			24006978	24-Jun-22
			24271828	14-Aug-22
			24383293	4-Sep-22
			24411526	10-Sep-22
	M00536660	8714729857600	21312747	27-Oct-20
			21865108	14-Mar-21
			22275742	19-Jun-21
			24411527	10-Sep-22
	M00536670	8714729857617	21376782	12-Nov-20
			21636753	19-Jan-21
			21724127	8-Feb-21
			21833853	7-Mar-21
			22007181	17-Apr-21
			22136472	17-May-21
			22195529	31-May-21
			22212529	5-Jun-21
			22522255	15-Aug-21
			22613956	5-Sep-21
			22858807	28-Oct-21
			23073638	11-Dec-21
			23321211	8-Feb-22
			23408729	26-Feb-22
			23875252	29-May-22
			24167479	24-Jul-22
			24229866	6-Aug-22
			24411528	10-Sep-22
	M00536680	8714729857624	21285272	20-Oct-20
			21568464	3-Jan-21
			21750673	14-Feb-21
			21865109	14-Mar-21
			22072355	2-May-21
			22613957	5-Sep-21
			23408730	26-Feb-22
	23492662	14-Mar-22		

Product Description	Material Number (UPN)	GTIN	Batch	Expiration Date	
Advanix™ Pancreatic Stents	M00536690	8714729857631	21568465	3-Jan-21	
			21724128	8-Feb-21	
			22072356	2-May-21	
			22250324	13-Jun-21	
			22480145	6-Aug-21	
			23902872	4-Jun-22	
	M00536700	8714729857648	21483842	6-Dec-20	
			21512596	13-Dec-20	
			21724129	8-Feb-21	
			21806787	28-Feb-21	
			21973221	9-Apr-21	
			22307744	26-Jun-21	
			22460195	1-Aug-21	
			23073639	11-Dec-21	
			23492663	14-Mar-22	
			24271829	14-Aug-22	
	M00536710	8714729857655	21750674	14-Feb-21	
			22036150	24-Apr-21	
			22647191	12-Sep-21	
			23902873	4-Jun-22	
	M00536720	8714729857662	21615214	15-Jan-21	
			21678783	29-Jan-21	
			22036151	24-Apr-21	
			22423474	24-Jul-21	
			23230411	22-Jan-22	
			23321212	8-Feb-22	
	M00536730	8714729857679	24167940	24-Jul-22	
			21542436	20-Dec-20	
			21897084	21-Mar-21	
				23230412	22-Jan-22



Please Complete the form even if you do not have any affected product & send it to
Your Local Office: «Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Verification Form – Urgent Medical Device Recall
"Name of the Product"
92440695-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)

Product Description	Material N° (UPN)	Lot / Batch / Serial N°	Customer PO	Qty Sent	Qty to return
«DESCRIPTION»					

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 _____ Department _____

Customer' SIGNATURE* _____ DATE* _____

* Required field

dd/mm/yyyy