



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

October 21, 2019

Dear Materials Manager / Field Action Contact:

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.

This recall affects all batches of the UPNs listed in Attachment 1 below. No other products or UPNs are impacted by this notification. Refer to the Reply Verification Form included with this notification package for the list of individual batches we have record of shipping to your facility. Use and distribution of any remaining unused product affected by this removal should cease immediately.

If you identify any affected product within your inventory, please segregate the product immediately and return it to Boston Scientific in accordance with the enclosed instructions. You will receive credit for all product returned to Boston Scientific.

If you are a distributor, please note that this removal is to the customer level. Please notify any customer who has received affected product.

Boston Scientific is notifying regulatory authorities of this removal as required.

Please read carefully through the enclosed instructions. Your local Sales Representative can answer any questions that you may have regarding this action. Please pass this notice to any healthcare professional from your organization who 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).

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

Sincerely,



Shannon M. Stanek, MLS(ASCP),
QIA(ASQ)
Sr. Project Lead
Boston Scientific
Field Action Team
[Redacted]
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Encl: Removal Instructions
Reply Form

Urgent Medical Device Removal – Instructions

The Reply Verification Tracking Form enclosed with this Notice must be completed and returned **even if you do not have any remaining affected units.**

1. Immediately discontinue use of and segregate affected product.

- Immediately review and identify any affected product in your inventory.
- Segregate this product in a secure location for return to Boston Scientific.
- If you are a distributor, please note that the removal depth is to the hospital level and the removal notification should be forwarded to your customers.

2. Complete and return the Reply Verification Tracking Form (RVTF).

- Complete the enclosed Reply Verification Tracking Form even if you do not have any product to return, following the directions on this page and on the Reply Verification Tracking Form.
- Return the Reply Verification Tracking Form as described below:

Email:

or

Fax to:

Please email or fax your Reply Verification Tracking Form(s) immediately:

- **Once Boston Scientific receives your completed form, a Returned Goods Authorization number can be sent to you at the email address you provided on the form.**
- **Once you receive the RGA number you can return the product as directed below, place the original form with returned products.**

3. Package/Ship the Removed Product.

- Package product that is being returned in an appropriate shipping box.
- Affix a shipping label to the outside of the shipping box.
- Write the RGA number in large print on the outside of the box, either on or near the shipping label.
- Seal the box, and return it to:

Attachment 1 – 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	10/27/2020
			21776485	2/21/2021
			22737577	10/1/2021
			23257631	1/27/2022
			24271827	8/14/2022
	M00536620	8714729857563	21776487	2/21/2021
			22136470	5/17/2021
			22896244	11/5/2021
			23902871	6/4/2022
	M00536630	8714729857570	21483840	12/6/2020
			21512594	12/13/2020
			21724125	2/8/2021
			21833851	3/7/2021
			22007180	4/17/2021
			22195528	5/31/2021
			22212528	6/5/2021
			22647190	9/12/2021
			22828072	10/21/2021
			23000367	11/27/2021
			23257632	1/27/2022
			23578453	4/1/2022
			23615959	4/8/2022
			23796006	5/14/2022
			24167478	7/24/2022
			24229865	8/6/2022
			24396823	9/8/2022
	M00536640	8714729857587	21973220	4/9/2021
			22522254	8/15/2021
			23837823	5/21/2022
	M00536650	8714729857594	21187998	9/27/2020
			21285271	10/20/2020
			21337147	11/2/2020
			21483841	12/6/2020
			21512595	12/13/2020
			21662812	1/25/2021
			21724126	2/8/2021
			21833852	3/7/2021
			21922988	3/27/2021
			22036149	4/24/2021
			22136471	5/17/2021
			22307745	6/26/2021

Attachment 1 – Product Listing (Continued)

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	M00536650 (Continued)	8714729857594	22359735	7/10/2021
			22613955	9/5/2021
			22700891	9/24/2021
			23035017	12/4/2021
			23295961	2/4/2022
			23492660	3/14/2022
			23541961	3/25/2022
			24006978	6/24/2022
			24271828	8/14/2022
			24383293	9/4/2022
			24411526	9/10/2022
	M00536660	8714729857600	21312747	10/27/2020
			21865108	3/14/2021
			22275742	6/19/2021
			24411527	9/10/2022
	M00536670	8714729857617	21376782	11/12/2020
			21636753	1/19/2021
			21724127	2/8/2021
			21833853	3/7/2021
			22007181	4/17/2021
			22136472	5/17/2021
			22195529	5/31/2021
			22212529	6/5/2021
			22522255	8/15/2021
			22613956	9/5/2021
			22858807	10/28/2021
			23073638	12/11/2021
			23321211	2/8/2022
			23408729	2/26/2022
			23875252	5/29/2022
			24167479	7/24/2022
			24229866	8/6/2022
			24411528	9/10/2022
	M00536680	8714729857624	21285272	10/20/2020
			21568464	1/3/2021
			21750673	2/14/2021
			21865109	3/14/2021
			22072355	5/2/2021
			22613957	9/5/2021
			23408730	2/26/2022
			23492662	3/14/2022

Attachment 1 – Product Listing (Continued)

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Product Description	Material Number (UPN)	GTIN	Batch	Expiration Date
Advanix™ Pancreatic Stents	M00536690	8714729857631	21568465	1/3/2021
			21724128	2/8/2021
			22072356	5/2/2021
			22250324	6/13/2021
			22480145	8/6/2021
			23902872	6/4/2022
	M00536700	8714729857648	21483842	12/6/2020
			21512596	12/13/2020
			21724129	2/8/2021
			21806787	2/28/2021
			21973221	4/9/2021
			22307744	6/26/2021
			22460195	8/1/2021
			23073639	12/11/2021
			23492663	3/14/2022
			24271829	8/14/2022
	M00536710	8714729857655	21750674	2/14/2021
			22036150	4/24/2021
			22647191	9/12/2021
			23902873	6/4/2022
	M00536720	8714729857662	21615214	1/15/2021
			21678783	1/29/2021
			22036151	4/24/2021
			22423474	7/24/2021
			23230411	1/22/2022
			23321212	2/8/2022
			24167940	7/24/2022
	M00536730	8714729857679	21542436	12/20/2020
			21897084	3/21/2021
			23230412	1/22/2022