

Urgent Medical Device Removal - Immediate Action Required

Encore™ 26 Inflation Device

Encore™ 26 Advantage Kit

NephroMax™ Kit

UroMax Ultra™ Kit

August 5, 2025

Dear Healthcare Professional,

Cc: Chairman Medical Board and relevant Head of Department:

Boston Scientific is initiating a removal of certain batches of the Encore™ 26 Inflation Device and certain batches of Encore™ 26 Advantage Kits, NephroMax™ Kits and UroMax Ultra™ Kits in which the impacted Encore 26 inflation devices are a component (see Appendix 1) due to the potential presence of foreign material.

The Encore 26 Inflation Device is used with balloon dilation catheters to create and monitor pressure in the balloon and to deflate the balloon. An internal investigation determined that during use, foreign material particles could migrate from affected Encore 26 Inflation Devices into a balloon dilatation catheter.

The Encore 26 Inflation Device may be used in a variety of clinical applications including interventional cardiology, neurovascular, endoscopy, urology and peripheral vascular procedures.

The most serious potential adverse health consequence associated with use in these different applications is as follows:

Cardiovascular	A life-threatening embolic event may occur, with a remote likelihood, through a cascade of events in which foreign material enters the balloon dilatation catheter and a balloon rupture occurs when already inserted in the patient.
Neurovascular	A life-threatening embolic event may occur, with a remote likelihood, through a cascade of events in which foreign material enters the balloon dilatation catheter and a balloon rupture occurs when already inserted in the patient.
Urology	Laceration/perforation requiring surgical intervention, with a remote likelihood, may result from deflation issues resulting from foreign material in the lumen of the balloon dilatation catheter.
Endoscopy	Obstruction at the biliary or pancreatic duct orifice leading to biliary obstruction or pancreatitis, inflammation, infection and additional intervention, with a remote likelihood, resulting from a cascade of events in which foreign material enters the balloon dilatation catheter and a balloon rupture occurs when already inserted in the patient.
Peripheral Vascular	An embolic event requiring surgical intervention may occur, with a remote likelihood, in which foreign material enters the balloon dilation

	catheter and a balloon rupture occurs when already inserted in the patient.
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Boston Scientific has received 18 complaints of foreign material in the Encore device, a rate of 0.0009%, including one (1) complaint with the cascade of events of foreign material in the Encore device in conjunction with a balloon rupture, a rate of 0.000046%. No patient harm has been reported in any of these complaints.

In all clinical applications noted above, the most common potential adverse health consequence is prolongation of the procedure as the Encore inflation device is exchanged for another inflation device if the foreign material is detected during preparation or use of the device. There is a remote chance the foreign material could impact the ability to inflate or deflate the balloon used with the Encore 26 inflation device. Impact to balloon inflation may result in a prolongation of the procedure to exchange the device for another inflation device. Deflation issues resulting from foreign material in the lumen of the balloon may require the balloon to be ruptured so it can be removed from the patient. Harms that could result from removing a non-deflated balloon or needing to rupture the balloon for removal may include: infection, inflammation, obstruction, pain, laceration/perforation, hemorrhage, stenosis and unretrieved device fragments. There is a remote chance that any of these harms may occur. Boston Scientific has not received any reports of these patient harms.

Boston Scientific recommends that patients who have been treated with an Encore inflation device should continue to follow standard of care and any additional patient management should be at the discretion of their physician on an individualized basis.

Instructions:

1. Further distribution or use of any remaining devices affected by this removal (see Appendix 1) should cease immediately.

Do NOT use affected devices and remove those devices from your facility's inventory. Segregate the units in a secure place until they can be returned to Boston Scientific.

2. Immediately post this information in a visible location near the affected devices to ensure it is readily accessible to all handlers and users of the device.
3. Forward this notice to any healthcare professional from your organization and to any facilities where affected devices have been transferred, including hospitals or sites within your network.

If you are a distributor, this notice must be forwarded to your customers to ensure notification of this device removal is carried out to the end-user level.

4. Complete and return the enclosed Reply Verification Tracking Form per the enclosed instructions on page four.
5. Return affected devices. **The entire Encore 26 Advantage Kit, NephroMax Kit, or UroMax Ultra Kit must be returned in order to be reimbursed.**



This removal affects only the devices and batches listed in Appendix 1 - Affected Product). No other material numbers or batches are impacted by this removal.

Please carefully read the Removal Instructions included with this notification. Your local sales representative can answer any questions you might have regarding this notification.

Affected worldwide regulatory authorities are being notified of this removal as required.

Any adverse events or quality concerns associated with use of these devices should be reported to Boston Scientific via email at ComplaintCallCenter@bsci.com or FDA's MedWatch Adverse Event Reporting program [www.fda.gov/MedWatch/report.htm or 1.800.FDA.1088 (332.1088)].

Patient safety is Boston Scientific's highest priority. As such, we are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. If you require additional assistance or more information regarding this communication, please contact your local Boston Scientific representative.

Sincerely,

A handwritten signature in black ink that reads "Kara Carter". The signature is written in a cursive style and is positioned above the printed name and title.

Kara Carter
Vice President, Global Quality

Encl: Removal Instructions
Reply Verification Tracking Form

Removal Instructions

The Reply Verification Tracking Form (RVTF) enclosed with this Removal Notice must be completed and returned even if you do not have any units from affected lots. Reach out to your local Boston Scientific representative with any questions.

1. Immediately discontinue use and segregate affected product.
 - If your facility removes product from the outer package and stores individual devices, it is very important that you carefully use the product table in Appendix 1.
 - When searching for affected UPN and batch numbers, the product information listed on your specific RVTF (enclosed with this letter) provides outer package UPN numbers and should be utilized when verifying product to return.
2. Complete and return the RVTF.
 - Indicate the quantity of SINGLE units you will be returning for credit.
 - Product is sold as singles, multi-packs and kits.
 1. Your RVTF lists the quantity of units shipped to your facility (NOT quantity of single devices).
 2. If you are returning multi-packs, to receive appropriate credit, you must indicate the number of **single** units on the RVTF.
3. Package and ship affected product and return to Boston Scientific..
4. Credit will be issued for all returned affected product once received and confirmed by Boston Scientific.

Appendix 1 – Affected Product

Product Description	Material Number (UPN)	GTIN	Lot	Expiration Date
Encore 26™ Inflation Device	H74904526011	08714729177029	34915076	9/24/2026
			35065978	10/15/2026
	H74904526052	08714729127062	34915078	9/24/2026
			34915220	9/24/2026
	M0067101140	08714729755814	34892421	9/20/2027
	M001151050	08714729183624	34966934	10/1/2026
	M001151062	08714729137542	34873498	9/18/2026
M00566670	08714729755241	35045668	10/11/2027	
Encore 26™ Advantage Kit	H74904527011	08714729180005	34783060	9/5/2026
			34849364	9/13/2026
			34873499	9/18/2026
			34942522	9/27/2026
			34976509	10/2/2026
			35017763	10/8/2026
			35065979	10/15/2026
	35067000	10/15/2026		
	H74904527052	08714729127048	34873681	9/18/2026
			34915075	9/24/2026
			34942524	9/27/2026
			34986473	10/3/2026
			34986475	10/3/2026
NephroMax™ Kit	M0062101180	08714729077589	35275630	7/19/2026
			35603649	7/20/2026
			35618255	7/20/2026
			35644223	7/20/2026
			35768091	7/25/2026
	M0062101600	08714729834540	35268077	3/11/2027
			35294478	3/14/2027
			35547681	3/12/2027
			35576896	3/12/2027
			35627459	3/22/2027
UroMax Ultra™ Kit	M0062251200	08714729341277	35536688	3/1/2026
			35538633	3/6/2026
			35538634	3/2/2026
			35543803	3/6/2026
			35543804	3/7/2026
			35572728	3/7/2026
			35678100	3/8/2026

UroMax Ultra™ Kit	M0062251210	08714729341284	35274797	7/1/2026
			35274799	6/15/2026
			35277223	7/2/2026
			35277224	6/14/2026
			35294475	7/2/2026
			35294476	6/8/2026
			35584203	7/9/2026
			35584215	6/1/2026
			35656798	5/31/2026
			35667482	6/26/2026
			35667483	6/7/2026
	M0062251220	08714729341291	35257438	8/17/2026
			35535450	8/20/2026
			35536202	8/22/2026
			35547680	8/22/2026
			35656799	8/17/2026
	M0062251230	08714729341307	35266389	9/7/2026
			35543805	9/7/2026
	M0062251240	08714729341314	35690647	9/27/2026
	M0062251260	08714729341338	35537838	9/24/2026
			35537839	9/24/2026
	M0062251290	08714729341369	35266391	5/8/2026
	M0062251300	08714729341376	35275806	8/10/2026
			35536992	11/15/2026
	M0062251310	08714729341383	35536991	1/2/2027
	M0062251350	08714729341390	35690648	12/3/2026
	M0062251360	08714729302421	35257611	12/19/2026
			35536990	1/2/2027
	M0062251370	08714729302438	35294477	1/29/2027
			35536689	1/28/2027



RECALL REMOVAL REPLY VERIFICATION TRACKING FORM
PRODUCT NAME: Encore 26 Inflation Device

Instructions: This form must be completed and returned in all cases even if you do not have any affected product.

Immediately complete form and Scan/e-mail to: _____ OR Fax to #: _____

Account #:	Customer Name:		
Contact Name:			
Address:			
City:	State:	Province:	Postal Code:
Country:			

Our records indicate you have received the following affected product:

UPN/Material Number	Lot/Batch/Serial Number	Quantity Shipped	Shipment Date	P.O. Number	Quantity Single Units to be Returned

Section to be filled out by Customer:

1. Please Indicate:

- We have checked all areas where affected product could be located and have determined we do not have any affected product.
- OR**
- We have found affected product and have quarantined as instructed in this Recall Notification. Please indicate the quantity to be returned (in single units) in the above table. To return affected product, follow the instructions provided within this notification or from your (country) local office.

Please also indicate:

Are you a Distributor? Yes, and we have notified all customers that have been shipped/sold affected product
 No

2. Sign and Date to acknowledge this Field Action Notification (must be completed):

Print Name: _____ Signature: _____ Date: _____

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