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<**Reference: 97422051-FA**> 5 August 2025

Urgent Field Safety Notice - Urgent Medical Device Recall
Encore™ 26 Inflation Device
Encore™ 26 Advantage Kit
NephroMax™ Kit
UroMax Ultra™ Kit

Dear Materials Manager and/or Healthcare Provider,

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. The recall is isolated to Encore 26 Inflation Device batches that contain a specific component which has the potential to produce foreign material. 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.

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.

Our records indicate that your facility has received some of the concerned product. **The table below (Appendix 1) provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN 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.

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 **29 August 2025**.

4- **If you have products to return,** please package them in an appropriate shipping box. **After receipt of the Verification Form, Boston Scientific will contact you to arrange return. The entire Encore 26 Advantage Kit, NephroMax Kit, or UroMax Ultra Kit must be returned in order to be reimbursed.**

5- Please pass this notice to any health 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.

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,

Kara Carter
Vice President, Global Quality

Encosedl: Appendix 1 Affected Product List
Reply Verification Tracking Form

Appendix 1- Affected Product List

Product Description	Material Number (UPN)	GTIN	Lot	Expiration Date
Encore^{TM} 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^{TM} 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^{TM} 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^{TM} 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^{TM} 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

<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
Encore™ 26 Inflation Device - Encore™ 26 Advantage Kit
NephroMax™ Kit - UroMax Ultra™ Kit

97422051-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 5 August 2025.

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	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.***
     Note: The entire Encore 26 Advantage Kit, NephroMax Kit, or UroMax Ultra Kit must be returned in order to be reimbursed.

TO RETURN PRODUCTS:
1. After receipt of the Verification Form, Boston Scientific will contact you to arrange return.
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