Boston Scientific International S.A.
EMEA Headquarters
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France
Tel 33 (0)1 39 30 97 00
Fax 33 (0)1 39 30 97 99
www.bostonscientific.com

<Hospital_Name>
<Users_Name>
<Department>
<Customer_Address>
<Zip_Code> <City>
<Country_Name>

<**Reference: 97601757-FA**>
SRN: US-MF-000004702

2 July 2026

Urgent Field Safety Notice - Urgent Medical Device Recall
Rapid Refill™ Continuous Injection System

Dear Materials Manager and/or Healthcare Professional,

Boston Scientific is initiating recall of specific lots of Rapid Refill™ Continuous Injection System ("Rapid Refill") due to a supplier-issued recall of the 10 mL syringe used in Rapid Refill.

Per the supplier, Medline Industries, the syringe may loosen or disconnect from the manifold, resulting in a loose connection or complete disconnection. This issue may make it difficult to connect the syringe, perform aspiration or injection, or maintain a leak-free system. Users may identify the issue during system priming, preparation, or clinical use through visible leakage or an unusually loose syringe connection. To date, Boston Scientific has received no complaints associated with this issue, and no injuries or adverse events have been reported to Boston Scientific.

The most common adverse health consequence reasonably foreseeable to occur is a prolonged procedure due to the need to adjust or replace the syringe or device. Alternative compatible syringes are commonly available in procedural settings. Additional potential harms include minor fluid leakage that may result in allergic reaction.

The most serious adverse health consequence identified by Medline Industries is air embolism. This risk is associated with vascular procedures that utilize vascular access. Rapid Refill is designed and marketed solely for endoscopic procedures and is not intended for vascular use. Based on Boston Scientific's assessment, the expected clinical impact during intended endoscopic use is limited.

Our records indicate that your facility has received some of the concerned product. **The table below (Attachment 1) provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN, 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 the 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 Single packs and 10-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.**

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- Immediately post this information in a visible location near the affected products to ensure this information is readily accessible to all handlers and users of the device.

3- **Please complete the attached Verification Form** even if you do not have any product to return.

4- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of <Customer_Service_Fax_Number> on or before **20 July 2026**.

5- **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.**

6- 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 National Competent Authority has been informed of this communication.
Any adverse events or quality concerns associated with use of these devices should be reported to Boston Scientific and Competent Authorities if appropriate.

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

Yours sincerely,

Conor Dolan
Vice President, Global Quality

Attachment: Verification Form

FOR BOSTON SCIENTIFIC INTERNAL USE ONLY
Account Email: <Contact Email>
Language: <Language(s)>
LFAC Team: <LFAC_Distribution_Email_Address>
Country Code-Sold to: <Country_Code>-<Sold_to_b>

Attachment 1 Affected Product

Description	Material # / UPN	GTIN	Lot #	Expiration Date Range
Rapid Refill™ Continuous Injection System	M00566001	08714729285151	33786611, 33825949, 33826026, 33949916, 33968571, 33968575, 34079981, 34153104, 34153413, 34153415, 34203075, 34203077, 34153411, 34203079, 34203115, 34386605, 34386609, 34386613, 34429656, 34429658, 34595249, 34693559, 34616613, 34616615, 34712433, 34763427, 34763967, 34805723, 34805725, 34805729, 35006995, 35006999, 35056793, 35208946, 35186845, 35208950, 35397314, 35208952, 35305436, 35498030, 35448316, 35498028, 35551523, 35626939, 35574463, 35688118, 35688460, 35828714, 35831703, 35848483, 35877768, 35995282, 36049415, 36159194, 36219882, 36294100, 36303614, 36332230, 31177006, 31180206, 31666278, 31329922, 31356107, 31666276, 31798400, 31798133, 31798135, 31798137, 31852246, 32162450, 32208753, 32255526, 32255528, 32496142, 32661870, 32696046, 32696050, 32696052, 32752697, 32773682, 32791475, 32791477, 32820865, 32838612, 32791479, 33119798, 32977346, 32977348, 33030942, 33120320, 33158008, 33158006, 33354311, 33354315, 33354317, 33403248, 33403252, 33696882, 33696884, 33696886, 33696888, 33750883, 33750885, 33750887, 36332232, 36497262, 36159192, 36587704, 36612263, 36739668, 36785215, 36785217, 36814560, 36845486, 36983883, 36983886, 37291592, 37059471, 37417957, 37417959, 37429808, 37456936, 37472523, 37585745, 37627037, 37654892, 37941477, 37974508, 38033021, 38033023, 38124799, 38143635, 38165214, 38182214, 38201123, 37959187, 38353956, 38374833, 38430201, 33968573, 34386611, 32838610, 38205377, 38429054, 34066207, 34429654, 34616611, 34712429, 34763971, 34805727, 35006997, 35448312, 35448314, 35626937, 35688021, 35848481, 35687399, 31616842, 31601573, 31616848, 31616850, 31616846, 32208755, 32455154, 35877766, 36776858, 37037796, 37200706, 37276220, 37291594, 37639238, 38154387, 35305438, 31797614, 33354313, 33696890, 36470789, 37309672, 37396601, 37407323, 37472521, 35056797, 35626933, 33786613, 33825951, 33950422, 34965218, 35056795, 36101020, 36100418, 31356105, 32208759, 32661868, 33030940, 33679650, 37059473, 37041524, 37633157, 37991645, 38137850, 38393609, 33968569, 34703963, 36319481, 33649863, 37019542, 37493275, 34616609, 34386607, 34763969, 34805721, 35942747, 31852244, 32977350, 33354319, 37884043, 38001944, 32752695, 37189280, 37612931, 38703180, 34429700, 33968567, 34017321, 34568306, 34712431, 34873735, 34873737, 34965420, 35007081, 35186843, 35208948, 35397312, 35448310, 35305600, 35626935, 35778515, 35778517, 35778513, 35989120, 36027670, 36049413, 36303612, 36319483, 36312073, 36353951, 36437019, 36517931, 36409546, 36537384, 36622267, 36750117, 36750119, 36994750, 36962014, 37407325, 37456934, 37766480, 37660978, 37764898, 37723376, 37991643, 38856580, 38178214, 38337853, 38326961, 38410111, 38414293, 38576233, 38586789, 38622115, 38633220, 38676778, 38649491, 38680582, 38864691, 38687308, 38876174, 38901702, 31170922, 31601571, 31616844, 31852242, 31852240, 32162448, 32208757, 32696048, 32723872, 32723874, 32838608, 32964550, 32977344, 33119794, 33119796, 33257466, 33334705, 33403250, 33649865, 33933383	5 March 2026 To 22 March 2029

<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
Rapid Refill™ Continuous Injection System
97601757-FA

1- We acknowledge receipt of the Boston Scientific Field Safety Notice dated 2 July 2026.

2- **Boston Scientific records indicate you have received the following affected products** *(additionally please check inventory against complete list of affected products 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** (Single 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- 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