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<Zip_Code> <City>
<Country_Name>

<**Reference: 97046436-FA**> 17 June 2026
SRN: US-MF-000004703

Urgent Field Safety Notice - Urgent Medical Device Recall Infinion™ CX Lead

Dear Materials Manager and/or Healthcare Professional,

Boston Scientific is initiating a voluntary recall of unused Infinion™ CX Leads as part of the planned transition to the next generation lead (Infinion Pro). This action does not affect the devices that have already been implanted. For leads already in use, continued routine follow-up is recommended.

Product Description
The Infinion CX 16-contact Leads are components of the Boston Scientific Spinal Cord Stimulator (SCS) Systems. A change to lead body configuration was implemented in Infinion Pro, which was designed to provide an enhanced durability profile.

Risk to Health
It was found that the lead body may be exposed to stress at the anchor site, which in some cases resulted in reports of high impedance or lead fractures. Over the period from Sept 2014 through April 2026, the rate of lead fractures observed is 1%.

Impedance testing is an integral part of the standard procedural follow-up for patients after SCS implantation. In the presence of an abnormal impedance measurement, the most frequently observed harm is inadequate stimulation. If reprogramming does not resolve the issue, additional intervention, including lead explant or replacement, may be required. The rate of high impedance reports resulting in additional intervention is approximately 4%. No additional patient monitoring beyond routine clinical follow-up is recommended.

Infinion CX Leads are no longer being distributed. Infinion Pro Leads are available in countries where regulatory approvals have been granted.

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

Material Description	Material	GTIN	Batch
INFINION CX LEAD KIT, 50CM	M365SC2317500	08714729861614	All
INFINION CX LEAD KIT, 70CM	M365SC2317700	08714729861638	

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the above 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 **3 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,

Richard Kirkendall
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>*

<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
Infinion™ CX Lead
97046436-FA

1- We acknowledge receipt of the Boston Scientific Field Safety Notice dated 17 June 2026.

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

Material N° (UPN)	Lot / Batch N°	Customer PO	Qty Sent	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