Boston Scientific

Urgent Medical Device Product Removal - Immediate Action Required

Artisan™ 70cm 2x8 Surgical Lead Kit
35cm and 55cm 8 Contact Extension Kits
Linear™ 3-4 50cm and 70cm 8 Contact Lead Kit
Precision™ M8 Adapter, 15cm

April 17, 2019

Dear Materials Manager / Field Action Contact:

Boston Scientific is initiating a voluntary removal of certain spinal cord stimulation leads, lead extensions, adapters, and deep brain stimulation lead extensions due to "Use by Date" that is later than the correct "Use by Date" displayed on the label of these products. While the "Use by Date" is incorrect, to date, none of the affected products have reached the allowed product shelf life and the earliest instance of these devices reaching their actual expiration date is September 2019.

No adverse health consequence is expected to occur from this issue. To date, Boston Scientific has received no complaints for the incorrect expiration date on the label. The devices meet all Boston Scientific design specifications and are expected to perform as intended.

Further distribution or use of any remaining product affected by this removal should cease immediately.

This removal affects only the part numbers (with associated serial numbers) listed in the table below and in Attachment 1. No other products are impacted by this notification.

Affected Product Listing

Product Description	Part Number (UPN)	GTIN	Serial Numbers
55cm 8 Contact Extension Kit	M365NM3138550	08714729820765	[redacted]
Artisan™ 70cm 2x8 Surgical Lead Kit	M365SC8216700	08714729779919	[redacted]
35cm 8 Contact Extension Kit	M365SC3138350	08714729760559	[redacted]

Linear™ 3-4 50cm 8 Contact Lead Kit	M365SC2352500	08714729789550	[redacted]
Linear™ 3-4 70cm 8 Contact Lead Kit	M365SC2352700	08714729789581	[redacted]
Precision™ M8 Adapter, 15cm	M365SC9218150	08714729888734	[redacted]
55cm 8 Contact Extension Kit	M365SC3138550	08714729760566	[redacted]

If you identify any affected products within your inventory, please segregate them immediately and return it to Boston Scientific in accordance with the enclosed instructions. You will receive replacements for all removed products 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 the affected product(s).

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 removal. 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 regret any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

[redacted]

Brendan Smith
Boston Scientific Quality Systems
763-494-1133
BSCFieldActionCenter@bsci.com

Encl: Removal Instructions
Reply Form

Health care professionals and consumers may report serious adverse events (side effects) or product quality problems with the use of this product to Boston Scientific by calling 1-866-868-4004 and to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm
Regular Mail: use postage-paid FDA form 3500 available at www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD, 20852-9787
Fax: (800) FDA-0178
Phone: (800) FDA-1088

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 affected units in the inventory**.

1. **Immediately segregate affected product(s)**.
   - Immediately remove all affected product(s) from your inventory.
   - Segregate product(s) in a secure location for return to Boston Scientific.
   - If you are a distributor, please note that the removal depth is to the customer 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 affected product to return. Follow the directions on this page and on the Reply Verification Tracking Form.
   - Verify if the product within your inventory is affected. If so, indicate on your Verification Form the part and serial number(s) that you will be returning.
   - Email or fax the Reply Verification Tracking Form to the BSC Field Action Center as described below:

     Email: **BSCFieldActionCenter@bsci.com**
     or
     Fax to: **Field Action Center 1-866-213-1806**

   Please email or fax your Reply Verification Tracking Form(s) immediately. You will be contacted by Boston Scientific and provided a Returned Goods Authorization (RGA) Number after your RVTF is received. When returning the product, place the original form with returned products.

3. **Package/Ship the affected removed product.**
   - Package any 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.
     - Feel free to use our Federal Express Number 9205-2515-6 to return this package via second day delivery.
   - Seal the box, and return it to: **Boston Scientific Corporation**
     Kerkrade Distribution Center
     Vestastraat 6
     6468 EX Kerkrade
     Netherlands
     RGA: _____