Boston Scientific

Urgent Medical Device Removal Notice
FFR Link

July 5, 2017

Dear Kootenai Health:

This letter is to notify you that Boston Scientific is initiating a removal of one (1) FFR Link from your facility following our determination that the product may have missed electrical testing during the manufacturing process. Use of a FFR Link which has not passed electrical testing may result in the inability to isolate the patient and/or user from electrical shock during high voltage conditions such as a power surge. No associated complaints have been received to-date.

Refer to table 1 for affected Material/Lot information. This removal does not include any product other than what is listed below. **Further distribution or use of the product affected by the removal should cease immediately**. A Boston Scientific Field Service Engineer will be visiting your facility to install a replacement unit and uninstall the unit listed below.

Table 1: Affected Product Listing

Product Description	Material Number (UPN) #	Lot/Batch #	Expiration Date
FFR Link	H7495551000	SPM01616	28-June-2044

We are notifying the appropriate worldwide regulatory authorities of this removal as required.

Boston Scientific is requesting that you complete the acknowledgment form and send it back to our facility to indicate the unit has been removed.

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

Sincerely,

[redacted]
Field Action Team Lead
763-494-1133
Shannon.Stanek@bsci.com

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 1-800-811-3211 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 Instructions

The Acknowledgment Form enclosed with this notification must be completed and returned.

1. **Identify the affected unit and ensure the unit is returned to Boston Scientific via the Field Service Engineer.**
2. **Complete and return the Acknowledgment Form.**
   Complete the enclosed Acknowledgment Form (even if you no longer have the affected product), following the directions on this page and on the form.
   Return the Acknowledgment Form to:

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