Boston Scientific

Important Medical Device Information
FFR Link

May 30, 2017

Dear Cox Health:

This letter is to notify you that Boston Scientific initiated 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. This issue resulted in no risk to patients or users of the product.

After learning of this issue, a Boston Scientific Field Service Technician proactively removed the unit (UPN H7495551000, serial SPM01975), sent it back to Boston Scientific for further investigation on May 15th and replaced it with a new FFR Link. No other lots are affected by this issue at your facility.

Affected regulatory authorities are being notified of this removal as required.

Boston Scientific is requesting that you complete the acknowledgement form and send it back to our facility to indicate receipt of this letter.

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]
Engineer Sr. QA
763-494-1133
Nicole.maloney@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