«Hospital_Name»
«Users_Name» - «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 90981465-FA

September, 2014

Urgent Field Safety Notice
Medical Device

OffRoad™ Re-Entry Catheter System

Dear «Users_Name»,

Boston Scientific is initiating a Field Safety Corrective Action (FSCA) for five (5) lots of the **OffRoad™ Re-Entry Catheter System**. The OffRoad™ Re-Entry Catheter System consists of two components, which are contained in an outer carton: the OffRoad™ Positioning Balloon Catheter and the OffRoad™ Micro-Catheter Lancet. Boston Scientific has become aware that the outer package carton for these five lots displays an incorrect expiration date that is two months past the actual expiration date. The actual expiration of the individual Positioning Balloon Catheter and Micro-Catheter Lancet contained within the outer carton is correctly displayed on the pouch and box labels of those components. No adverse health consequence is expected to occur from this issue and Boston Scientific has received no complaints for the incorrect expiration date.

Our records indicate that your facility received some of the concerned product. **The table below provides a complete list of all affected products**, including Product Description, Material Number (UPN), Lot/Batch numbers and expiration date. **Please note that only the material listed in the table below is affected. No other Boston Scientific product is involved by this Field Safety Notice.**
Further distribution or use of any remaining product affected by this action should cease immediately.

Product Description	Material Number (UPN)	Catalog Number	Lot	Expiration Date
OffRoad™ Re-Entry Catheter System	H74939202100540	39202-100540	16949014	May 2017
			16805826	March 2017
			16514008	November 2016
			16514006	November 2016
			16458224	October 2016

INSTRUCTIONS:

1. **Please immediately discontinue use of the Boston Scientific product** listed above **and remove all of the affected units from your inventory** (whether in Cath Lab., Radiology, Fluoroscopy Suite, Interventional Operating Room, Central Supply, Shipping & Receiving and any other relevant location). **Segregate the units in a secure place, pending return to Boston Scientific.**

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

3. **When completed,** please **fax the Verification Form** to your local Boston Scientific Office to the attention of «Customer_Service_Fax_Number» **on or before 23 September 2014.**

4. **If you have products to return,** please package them in appropriate shipping box and **contact** «Customer_Service_Tel» of **your local Boston Scientific Office,** to arrange return.

5. Please pass this notice to any health professional of your organization that need 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 Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause and we appreciate your understanding as we take action to ensure patient safety and customer satisfaction.

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

Yours sincerely,

Quality Department
Boston Scientific International S.A.

Attachment: Verification Form