Boston Scientific International S.A.
ZAC Paris Nord II/Bât Emerson - 33 rue des Vanesses – 93420 Villepinte
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France

Tel 33 (0)1 48 17 47 00
Fax 33 (0)1 48 17 47 01
www.bostonscientific.com

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

Reference: 91069919-FA

August XX, 2015

Urgent Field Safety Notice - Medical Device Removal
Spiroflex® AngioJet® Thrombectomy Set
AngioJet® SOLENT™ omni
AngioJet® SOLENT™ dista
AVX® Thrombectomy Set

Dear «Users_Name»,

Boston Scientific, in cooperation with Bayer Medical Care, is initiating a recall on distributed product in the scope of a 2014 Bayer Interventional AngioJet recall. The Bayer Interventional recall was initiated due to units having incorrect 'use by' dates on the label that were one month beyond the actual use by date. The correct use by date is 2015-11 (November 30, 2015) but the date on the label is 2015-12 (December 31, 2015). The affected products are still within their valid shelf-life through November 30, 2015. No adverse health consequence is reasonably expected to result from the incorrect use by 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.**
Further distribution or use of any remaining product affected by this action should cease immediately.

Product Description	Material Number (REF)	Lot	Use by Date
Spiroflex® AngioJet® Thrombectomy Set	106553-004	163580	30 November 2015
AngioJet® SOLENT™ omni	109681-004	162185	
	109681-001	162318	
AngioJet® SOLENT™ dista	111303-001	161905	
AVX® Thrombectomy Set	105039-001	163390	

INSTRUCTIONS:

1. **Please immediately discontinue use of the Boston Scientific product** listed above **and remove all of the affected units from your inventory, irregardless of where these units are stored in your facility**. **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 **send the Verification Form** to your local Boston Scientific Office to the attention of «Customer_Service_Fax_Number» **on or before XX August 2015.**

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,

[redacted]

Quality Department
Boston Scientific International S.A.

Attachment: Verification Form