Please Complete the form even if you do not have any affected product & send it to Your Local Office:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Verification Form – Urgent Medical Device Recall
"Name of the Product"

91133341-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date_notif_sent».

2. **Boston Scientific records indicate you have received the following affected product** *(additionally please check inventory against complete list of affected product provided)*

Product Description	**Material N° (UPN)**	**Lot / Batch N°**	**Customer PO**	**Qty Sent** (Units)	**Qty to return** (Units)
«DESCRIPTION»					

3. We confirm that all areas where affected product could be located have been checked.

4. **TICK ONE OF THESE STATEMENTS*****, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»

- ❑ We do not have any affected product.
- ❑ We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please* ***add the UPN, Lot/Batch/Serial number and the quantity to return.***

TO RETURN PRODUCTS:
1. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
2. Prepare the package
3. Follow the instructions given by your Local Office about collection of the package

NAME* _____Title _____

Telephone _____ Department _____

Customer' **SIGNATURE*** _____ **DATE*** _____
* Required field dd/mm/yyyy

Boston Scientific International S.A.
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Tel 33 (0)1 48 17 47 00
Fax 33 (0)1 48 17 47 01
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«Hospital_Name»
«Users_Name»- «Department»
«Customer_Address»
«Zip_Code» «City» - «Country_name»

Reference: 91133341-FA

xx March 2016

Field Safety Notice
Urgent Medical Device Recall
WATCHMAN FLX™ Left Atrial Appendage (LAA) Closure Device

Dear «Users_Name»,

Boston Scientific is implementing a voluntary Medical Device Removal of all non-implanted WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Devices. The reason for this action is that Boston Scientific has received an increased number (6 of 207 – 2.9%) of implant embolization reports both during procedure (2) and post procedure (4) on the WATCHMAN FLX LAAC Devices.

Each embolized FLX device was successfully retrieved percutaneously without permanent embolization. Note: one patient died due to complications related to a post-operative infection after percutaneous removal of their FLX device.

For the WATCHMAN FLX LAAC devices that have been previously implanted, continue to follow patients in accordance with the Directions for Use, including specified follow-up Trans-Esophageal Echocardiographic (TEE) imaging.

This removal affects all catalogue and lot numbers of the WATCHMAN FLX LAAC Device included in the table below. Further distribution or implantation of this device should cease immediately.

Note: The current generation WATCHMAN LAAC device and the WATCHMAN Access System continue to be available and are not affected by this removal.

Product Description	Catalogue #	Lot #
WATCHMAN FLX™ LAAC Device with Delivery System	WS5020	18225672, 18225673, 18225674, 18396812, 18401612, 18459184, 18581834, 18603231, 18682283, 18688431, 18688432, 18707084, 18736313, 18751534, 18751536, 18838165, 18845130, 18875658, 18900177, 18914801, 18914802, 18929298
	WS5024	18396813, 18401613, 18408201, 18408202, 18435076, 18480472, 18492730, 18581835, 18591486, 18603232, 18682284, 18682288, 18688428, 18707085, 18736314, 18742868, 18751537, 18838166, 18866426, 18900176, 18914803, 18915361, 18934783, 18944586, 18972521, 18979870

	WS5027	18396814, 18408203, 18409435, 18435077, 18459185, 18492731, 18581836, 18591490, 18682285, 18682289, 18707086, 18736315, 18751538, 18751539, 18838167, 18866427, 18876065, 18908883, 18914808, 18914809, 18914810, 18914811, 18914812, 18929299, 18934786, 18944584, 18944587, 18972522, 18979879, 18989184
	WS5031	18396811, 18408205, 18435078, 18459186, 18534734, 18581837, 18591358, 18682286, 18707087, 18736316, 18752110, 18832856, 18845134, 18876063, 18893436, 18914813, 18934784, 18944588, 18980043, 18989186
	WS5035	18182797, 18225668, 18225671, 18401059, 18435079, 18483583, 18581838, 18682287, 18707088, 18736317, 18751760, 18832857, 18845135, 18876066, 18900178, 18914814, 18934785

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the list 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 return the Verification Form to your local Boston Scientific office** to the attention of «Customer_Service_Fax_Number» on or before **xx April 2016**.

4- **If you have products to return,** please package them in an 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]

Attachment: - Verification Form

Boston Scientific International S.A.