

«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,

Marie Pierre Barlangua  
 Quality Department  
 Boston Scientific International S.A.

Attachment: - Verification Form