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

Reference: 91133341AB-FA

XX September 2016

Field Safety Notice - Important Medical Device Information
WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device

Dear «Users_Name»,

On March 29, 2016, Boston Scientific (BSC) initiated a voluntary Medical Device Removal of all non-implanted WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) devices. For previously implanted WATCHMAN FLX LAAC devices, the notice sent to your facility recommended to continue to follow patients in accordance with the Directions for Use (DFU), including specified follow-up at 45 days using Trans-Esophageal Echocardiographic (TEE) imaging.

Subsequently, BSC has received communications from Competent Authorities. As a result of these communications, BSC is initiating a recommendation to expand follow-up schedule for patients implanted with a WATCHMAN FLX LAAC device to determine whether the device remains implanted. Therefore, in addition to the current DFU requirement to perform patient follow-up at 45 days using TEE, it is also recommended that patient follow-up be performed at 6 and 12 months with TEE.

During these additional imaging visits it remains the individual physician's clinical decision to determine if an alternative to TEE is appropriate in order to determine whether the device remains implanted.

This Field Safety Notice affects all Catalogues and Lot Numbers of the WATCHMAN FLX LAAC Device included in the table below. Our records indicate all affected facilities have provided confirmation that all of their unused products have been returned to BSC.

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

WATCHMAN FLX™ LAAC Device with Delivery System	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- Immediately post this information in a visible location near the product to ensure this information is easily accessible to all physicians that have used the WATCHMAN FLX LAAC device.

2- **Please complete the attached Acknowledgement Form** even if you do not have any affected product.

3- **When completed, please return the Acknowledgement Form to your Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **XX October 2016**.

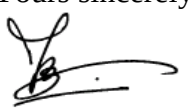
4- Please pass on this notice to any healthcare professional from your organization that need to be aware and to any organization where the potentially affected devices have been transferred (If appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Although Boston Scientific is not physically recalling any product, 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 act 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: Acknowledgement Form

Please complete the form & send it to Your Local Office:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «Users_Name» - «City» - «Country_name»

Acknowledgement Form – Field Safety Notice

WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device

91133341AB-FA

I acknowledge receipt of the Boston Scientific Field Safety Notice

dated xx September 2016

for the WATCHMAN FLX™ Left Atrial Appendage Closure (LAAC) Device

and took action as required in the "Instructions" of the letter.

NAME* _____ **TITLE** _____

Telephone _____ Email _____

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