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Reference: 91033431-FA

XX August 2015

Urgent Field Safety Notice
Important Medical Device Information
WATCHMAN® Left Atrial Appendage Closure Device with Delivery System and WATCHMAN® Access System Access Sheath with Dilator

Dear «Users_Name»,

Boston Scientific (BSC) is initiating a voluntary Field Safety Notice for the WATCHMAN technology, which includes the WATCHMAN Left Atrial Appendage (LAA) Closure Device with Delivery System and the WATCHMAN Access System.

BSC has determined cross-threading of the hemostasis valve may occur if the valve is tightened with the dilator in place, potentially preventing subsequent sealing of the valve when desired. This Field Safety Notice reinforces existing Directions for Use (DFU) and provides further guidance regarding the correct use of the hemostasis valve in order to avoid cross-threading and to securely seal the valve, minimizing the potential for undesirable blood leakage.

No product is being recalled and you are not required to return product to Boston Scientific.

Note that there is no impact to previously implanted devices.

Action Required

It is very important that you read this entire Field Safety Notice and ensure that all users of the WATCHMAN LAA Closure Device with Delivery System and WATCHMAN Access System are aware of this Field Safety Notice (please refer to the affected list of products attached). **You must also complete the enclosed Acknowledgment Form and return it to Boston Scientific, indicating that you have received, read, and understood the important information contained in this Field Safety Notice.**

Updated Directions for Use

The following sections of the WATCHMAN LAA Closure Device with Delivery System and the WATCHMAN Access System DFUs clarify correct use of the hemostasis valve and interaction between the access sheath and dilator. The additions to the current DFU are highlighted in **blue**:

Applicable to WATCHMAN LAA Closure Device with Delivery System and the WATCHMAN Access System DFUs:

3. Prepare WATCHMAN Access System.
Note: Inspect sterile package and WATCHMAN Access System prior to use. If sterile barrier, labeling, packaging, or device have been compromised in any way, DO NOT USE.

A. Remove access sheath and dilator from package under sterile conditions.
B. Inspect prior to use to ensure no damage.
C. Flush access sheath and dilator with sterile saline prior to use.
D. Insert dilator into hemostasis valve of access sheath until the two snap together.

Note: *Do not tighten the hemostasis valve while the dilator is inserted in the WATCHMAN Access System. The dilator by itself will occlude the lumen of the WATCHMAN Access System creating hemostasis. Tightening the valve onto the dilator may damage the valve threads, which can lead to subsequent difficulty in closing the valve and an incomplete seal, once the dilator is removed.*

4. Advance WATCHMAN Access System over guidewire into left atrium (LA). As access sheath nears center of LA, unsnap the access sheath from the dilator, hold dilator and advance access sheath into initial position in LA or ostium of Left Upper Pulmonary Vein (LUPV).
PRECAUTION: *Use caution when introducing the WATCHMAN Access System to prevent damage to cardiac structures.*

5. Remove dilator and guidewire, leaving access sheath in LA or LUPV. Allow back bleed to minimize potential for introducing air before tightening the hemostasis valve. Flush the access sheath with saline.

If continued back bleed is observed from the valve after the dilator is removed despite attempting to close it, loosen the valve cap (counter-clockwise rotation) until the cap spins freely. Then re-attempt closure of the valve while exerting gentle forward pressure on the valve cap during closure (clockwise rotation) to ensure proper engagement of the valve thread. While these steps are being undertaken, manual occlusion of the valve opening using a gloved finger is recommended to minimize blood loss.

Note: These steps may be repeated if necessary. However, if this does not mitigate the blood leak, the user should remove and replace the WATCHMAN Access Sheath before proceeding with the procedure.

(Continue to follow existing DFU instructions)

Applicable to the WATCHMAN LAA Closure Device with Delivery System DFU only:

8. Loosen hemostasis valve of the WATCHMAN Access Sheath allowing back bleed before inserting the WATCHMAN Delivery System. Note: Hemostasis valve should spin freely (fully open).

Note: Tightening the valve onto the WATCHMAN Delivery System may damage the valve threads, which can lead to subsequent difficulty in closing the valve and an incomplete seal, once the WATCHMAN Delivery System is removed.

(Continue to follow existing DFU instructions)

Our records indicate that your facility received one or more of the affected products subject to this Field Safety Notice. **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.

Product Description	Material/UPN	Lot/Batch Number	Expiration Date
WATCHMAN® Left Atrial Appendage Closure Device with Delivery System	M635WS21060	See attached list	
	M635WS24060		
	M635WS27060		
	M635WS30060		
	M635WS33060		
WATCHMAN® Access System	M635TS10060		
	M635TS20060		
	M635TS40060		

INSTRUCTIONS:

1. **Please read carefully the Field Safety Notice and immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the 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 local Boston Scientific office** to the attention of «Customer_Service_Fax_Number» on or before **xx September 2015.**

4. Please pass on 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).

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 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.

Attachments: - Acknowledgement Form
- List of affected product

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

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

Acknowledgement Form – Important Medical Device Information

WATCHMAN® Left Atrial Appendage Closure Device with Delivery System and WATCHMAN® Access System Access Sheath with Dilator

91033431-FA

I acknowledge receipt of the Boston Scientific Field Safety Notice

dated xx August 2015 for the

WATCHMAN® Left Atrial Appendage Closure Device with Delivery System

and

WATCHMAN® Access System Access Sheath with Dilator

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

NAME*_____Title _____

Telephone _____ Department _____

Customer' **SIGNATURE***_____**DATE***_____
* Required field DD/MM/YYYY