Boston Scientific

# Urgent Field Correction – Immediate Action Required

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

**Date:** 26 August 2015

Dear (please add the customer contact name):

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

**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)*

**Affected Product Information**
Our records indicate that your facility received the WATCHMAN LAA Closure Device with Delivery System and/or the WATCHMAN Access System. The table below provides a complete list of all affected products, including Product Description, Material Number (UPN), Lot/Batch number and Expiration Date. Please note that only the product listed in the table below is affected.

**No other Boston Scientific product is involved with this Field Correction.**

**Affected Product Listing**

| Product Description | Material/UPN | Lot/Batch Number | Expiration Date |
|---|---|---|---|
| WATCHMAN® Left Atrial Appendage Closure Device with Delivery System | M635WC21060 | See Attached Affected Product Listing | 31 AUG 2015 to 31 AUG 2018 |
| | M635WC24060 | | |
| | M635WC27060 | | |
| | M635WC30060 | | |
| | M635WC33060 | | |
| | M635WS21060 | | |
| | M635WS24060 | | |
| | M635WS27060 | | |
| | M635WS30060 | | |
| | M635WS33060 | | |
| | M635WU21060 | | |
| | M635WU24060 | | |
| | M635WU27060 | | |
| | M635WU30060 | | |
| | M635WU33060 | | |
| WATCHMAN® Access System | M635TC10060 | | |
| | M635TC20060 | | |
| | M635TS10060 | | |
| | M635TS20060 | | |
| | M635TS40060 | | |
| | M635TU10060 | | |
| | M635TU20060 | | |
| | M635TU40060 | | |

**If you are a distributor, please note that the impact of this Field Correction is to the hospital level and it should be forwarded to your customers without delay.**

All affected worldwide regulatory authorities are being notified of this Field Correction as appropriate.

Please read carefully through the enclosed Field Correction Instructions. Your local Sales Representative can answer any questions that you may have regarding this Field Correction.

We appreciate your understanding as we take action to ensure customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

Sincerely,

Sincerely,

[Contact]
[Title]
[Phone]
[Email]

Encl: Field Correction Instructions
Customer Acknowledgement Form

# Field Correction Instructions - Immediate Action Required

The Customer Acknowledgment Form enclosed with this Field Correction must be completed and returned by 20th Sep, 2015, **even if you no longer have any affected product**.

1. **Immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the WATCHMAN LAA Closure Device with Delivery System and WATCHMAN Access System.**

2. **Complete and return the Customer Acknowledgment Form.**
   - Complete the enclosed Customer Acknowledgment Form (even if you no longer have any of the products), following the directions on this page and on the form.
   - Return the Customer Acknowledgment Form:

     **Email:** **[Email]**

     or

     **Fax to:** **[Fax]**

**Please email or fax your Customer Acknowledgment Form immediately upon completing the steps above.**