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

**<Reference: 92630745-FA>** xx November 2020

# Urgent Field Safety Notice - Urgent Medical Device Recall
# LOTUS Edge™ Valve System

Dear «Users_Name»,

Boston Scientific (BSC) is voluntarily implementing a removal of the unused inventory of the LOTUS™ Edge Valve System.

There is no safety issue for patients who have previously received a LOTUS Edge valve. The valve continues to show acceptable clinical performance post-implant.

**Description:**
The Lotus Edge delivery system is a complex design which requires users to execute a series of placement, assessment and release steps, in accordance with the Instructions for Use, to allow maximum flexibility to recapture, reposition or remove the valve. A technical requirement exists with the LOTUS Edge delivery system for the user to perform visual inspection to confirm proper orientation of system components prior to locking the valve. Failure to execute the visual inspection correctly prior to locking the valve is a known and anticipated risk during the deployment process which can lead to the inability to release the delivery system. The most severe health consequence may result in surgical intervention and associated harms including stroke, vessel trauma or death. The visual inspection, when correctly conducted, has been shown to be highly effective in identifying and mitigating the delivery system risk.

To overcome these delivery system complexities in the short term, BSC has made significant investments in physician education. This includes a comprehensive training program for physicians in addition to the use of proctors and BSC field representatives, who support cases. This global training program and case support is used as an ongoing method of risk mitigation in the field during LOTUS Edge deployment.

The aforementioned complications remain within acceptable and documented levels. In order to safely increase commercial use of the valve, BSC has examined the ability to expand its comprehensive LOTUS Edge training program and is evaluating the commercial scalability of design enhancements to reduce the delivery system complexities. However, given current uncertainties, BSC has made the difficult decision to remove all product from the field.

**Actions to be Taken:**

BSC recommends that patients who have had a LOTUS Edge valve continue with their routine follow-up care. There is no need to take any additional action for these patients.

This action affects all UPNs and batches of the LOTUS Edge Valve System.

Further distribution or use of any remaining affected product should cease immediately.

**Table 1: Affected Product Listing**

| Product Description | UPN | GTIN | Lot Number | Expiration Date Range |
|---|---|---|---|---|
| LOTUS™ Edge Valve System | H749LVS230 | 08714729940814 | All lot numbers | All non-expired inventory |
| | H749LVS250 | 08714729940821 | | |
| | H749LVS270 | 08714729940838 | | |
| | H749LVSUS230 | 08714729960904 | | |
| | H749LVSUS250 | 08714729960911 | | |
| | H749LVSUS270 | 08714729960928 | | |
| | H749LVSCL230 | 08714729905592 | | |
| | H749LVSCL250 | 08714729905608 | | |
| | H749LVSCL270 | 08714729905615 | | |

**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**, regardless 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** for the attention of **«Customer_Service_Fax_Number»** on or before **XX December 2020**.

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 healthcare professional from your organization that needs 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 act to ensure patient safety and customer satisfaction. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

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

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

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

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# Verification Form – Urgent Medical Device Recall
# LOTUS Edge™ Valve System
**92630745-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)*

| Material N° (UPN) | Lot / Batch N° | Customer PO | Qty Sent | Qty to return |
|---|---|---|---|---|
| | | | | |

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 _____ Email _____

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