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

Reference: 91087822-FA 16th September 2015

Urgent Field Safety Notice - Medical Device Removal
EndoVive™ One Step Button™
EndoVive™ Button Decompression Tube
EndoVive™ Low Profile Replacement Button

Dear «Users_Name»,

Boston Scientific has become aware that specific lots of the EndoVive One Step Button, EndoVive Button Decompression Tube, and EndoVive Low Profile Replacement Button may contain EndoVive Button Decompression Tubes with a protrusion that could impede its ability to be introduced or removed from the PEG Button. The EndoVive Button Decompression Tube is a single use, disposable device used to open the non-reflux valve in the EndoVive One Step Button and Replacement Button, to allow air to escape from the stomach. It is a small, blue plastic piece that is inserted into the One Step Button.

A user attempting to insert the decompression tube adapter will feel increased resistance when the protrusion contacts the button, and the user may then decide to pull out the decompression tube adapter, leading to delay of decompression. If the user applies additional force to fully insert the decompression tube adapter, it could dislodge the button into the stomach. If the decompression tube adapter is successfully inserted, then the increased resistance during removal could lead to pulling the entire EndoVive Button out of the body, which would require surgical re-insertion. It is possible, though a remote occurrence, that the protrusion could lead to a tear or perforation of the button tube, which would allow for exposure to the peritoneal cavity which could then lead to infection (peritonitis).

Our records indicate that your facility received some of the concerned product. **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.**
Further distribution or use of any remaining product affected by this action should cease immediately.

Product Description	Material Number (UPN)	Lot	Expiration Date
EndoVive™ Low Profile Replacement Button	M00568330	18210123	May 31, 2018
		18231256	May 31, 2018
		18249784	May 31, 2018
		18276188	June 30, 2018
		18310069	June 30, 2018
EndoVive™ One Step Button™	M00568510	18296155	May 31, 2018
EndoVive™ Button Decompression Tube	M00580471	18262588	June 30, 2018

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product** listed above **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 **send the Verification Form** to your local Boston Scientific Office to the attention of Fax 01442 411816 – Email: UK-Quality@bsci.com **on or before 29th September 2015.**

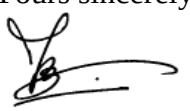
4- **If you have products to return,** please package them in appropriate shipping box and **contact** Cas Sherrard –Tel: 01442 411731 of **your local Boston Scientific Office,** to arrange return.

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

Please Complete the form even if you do not have any affected product & send it to Your Local **Office**:
Fax: 01442 411861 – Email: UK-Quality@bsci.com

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Verification Form – Urgent Medical Device Recall
"Name of the Product"
91087822-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 16th September 2015

2. **Boston Scientific records indicate you have received the following affected product**
(additionally please check inventory against complete list of affected product provided)

Product Description	**Material N° (UPN)**	**Lot / Batch N°**	**Customer PO**	**Qty Sent** (Units)	**Qty to return** (Units)
«DESCRIPTION»					

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 Fax: 01442 411816 – Email UK-Quality@bsci.com

- ❑ 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 Cas Sherrard - Tel 01442 411731 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 _____ Department _____

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