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

Reference: 91130383-FA

XX June 2016

Field Safety Notice - Urgent Medical Device Product Advisory
Boston Scientific Xenform™ Soft Tissue Repair Matrix

Dear «Users_Name»,

This notification is being sent to inform you of updates that Boston Scientific has made to the Directions for Use (DFU's) for our Xenform Soft Tissue Repair Matrix product listed in this notice.

In order to enhance patient and physician information regarding the use of our devices and to provide you with comprehensive information based on published literature and post-market data, we have made revisions to the Directions for Use (DFU) for the products referenced below. These updates include changes to ensure consistency across similar product lines. In addition two precaution statements are being added.

The following highlights the new Precautions that have been added. Please refer to this advisory in addition to the Directions for Use provided with the Xenform Soft Tissue Repair Matrix product to ensure that you have the latest information.

BSC has made revisions to the Directions for Use (DFU) for these products

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.

Precautions

- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal or transabdominal route.
- The use of mesh in urogynecologic procedures such as the treatment of pelvic organ prolapse, regardless of the route of delivery (transvaginal or transabdominal), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, ureter and bowel. Treatment of the erosion may require surgical removal.

Adverse Events

The following Adverse Event and text addition in blue font is being added to the DFUs:

- Pain, ongoing pain, discomfort, irritation;

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

Affected Product Information

Our records indicate that your facility has received Xenform™ Soft Tissue Repair Matrix products. The table below provides a complete list of all affected products including Product Description and Material Number (UPN). Please note that only the products listed in the table below are the subject of this product advisory.

Affected Product Listing

Product Description	UPN
Xenform™ Soft Tissue Repair Matrix, 2cm x 7cm	M0068302410
Xenform™ Soft Tissue Repair Matrix, 4cm x 7cm	M0068302430
Xenform™ Soft Tissue Repair Matrix, 6cm x 10cm	M0068302450
Xenform™ Soft Tissue Repair Matrix, 8cm x 12cm	M0068302470

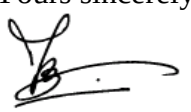
INSTRUCTIONS:

1. **Please complete the attached Acknowledgement Form**
2. **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 June 2016.**

Your local Sales Representative can answer any questions that you may have regarding this product advisory.

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.

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» - «City» - «Country_name»

Acknowledgement Form – Important Medical Device Information

Boston Scientific Xenform™ Soft Tissue Repair Matrix

91130383-FA

I acknowledge receipt of the Boston Scientific Field Safety Notice

dated XX June 2016

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

NAME*_____Title _____

Telephone _____ Department _____

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