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«Hospital_Name»
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Reference: 91130383-FA

XX June 2016

Field Safety Notice - Urgent Medical Device Product Advisory
Boston Scientific Pelvic Organ Prolapse Devices

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 Pelvic Organ Prolapse products 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.

The following highlights the new Warnings and Precautions that have been added. Please refer to this advisory in addition to the Directions for Use provided with the products to ensure that you have the latest information for the following products:

Pelvic Floor Repair Systems

- Uphold™ LITE Vaginal Support System with Capio™ SLIM
- Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior with Capio™ SLIM
- Upsylon™ Y Mesh Kit with Colpassist™ Vaginal Positioning Device

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.

Applicable to Uphold LITE Device and Pinnacle LITE Posterior Device DFU:

Warnings

The following two Warnings are being added to the Warnings section of the DFU's for Uphold LITE and Pinnacle LITE Posterior Devices. These warning statements are currently included the Upsylon Y Mesh DFU and are being added to the Uphold LITE Device and Pinnacle LITE Device DFUs to align the synthetic mesh warning statements across all Boston Scientific Products indicated for pelvic organ prolapse

- Mesh is considered a permanent implant. Removal of mesh or correction of mesh-related complications may involve multiple surgeries.
- Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

Applicable to All Affected Product DFUs: Uphold LITE, Pinnacle LITE Posterior and Upsylon Y Mesh:

Precautions

The following Precautions are being added to the DFU's for the above listed products:

- 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 polypropylene 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 current 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.

Applicable to Upsylon Y Mesh DFU:

Adverse Event

The following Adverse Events and text addition in blue font is being added to the Upsylon Y Mesh DFU:

- Pain, ongoing pain
- Post-operative bowel obstruction.

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 one or more of the affected products. The table below provides a complete list of all pelvic floor repair devices for pelvic organ prolapse (POP). Please note that only the products listed in the table below are the subject of this product advisory.

Affected Product Listing

Product Description	UPN
Uphold™ LITE Vaginal Support System with Capio™ SLIM	M0068318170
Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior with Capio™ SLIM	M0068318150
Upsylon™ Y Mesh Kit with Colpassist™ Vaginal Positioning Device	M0068318220

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 Pelvic Organ Prolapse Devices

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