

«Hospital\_Name»

«Users\_Name»- «Department»

«Customer\_Address»

«Zip\_Code» «City» - «Country\_name»

**Reference: 92378480-FA**

29 April 2019

**Urgent Field Safety Notice** (for Distributor) - **Medical Device Withdrawal**  
***Xenform™ Soft Tissue Repair Matrix***  
***Uphold™ Lite with Capiro SLIM Vaginal Support System***  
***Polyform™ Synthetic Mesh***  
***Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior***

Dear «Users\_Name»,

Boston Scientific is implementing a withdrawal of the following products indicated for transvaginal placement of pelvic organ prolapse:

- Xenform™ Soft Tissue Repair Matrix
- Uphold™ LITE with Capiro SLIM Vaginal Support System
- Polyform™ Synthetic Mesh
- Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior

On Tuesday, April 16, 2019, the United States Food and Drug Administration (FDA) ordered all manufacturers of surgical mesh for transvaginal repair of pelvic organ prolapse to stop selling products immediately and withdraw all products from the US market. FDA does not believe sufficient clinical evidence is available to assure the benefits of these devices outweigh their probable risks; for the US market this withdrawal was specific to only Xenform™ Soft Tissue Repair Matrix and Uphold™ LITE with Capiro SLIM Vaginal Support System

Based on this FDA decision and the global regulatory environment regarding transvaginal mesh for this indication, BSC has now made the decision to voluntarily withdraw from inventory, all products listed above from the rest of the world, which are indicated for the transvaginal repair of pelvic organ prolapse.

## **Clinical Recommendations**

Boston Scientific recommends that patients who have had transvaginal mesh placed for the surgical repair of pelvic organ prolapse should continue with their annual, other routine check-ups, and follow-up care. There is no need to take any additional action if patients are satisfied with their surgery and are not having any complications or symptoms.

**Next Steps**

Following is a list of affected products in scope of this action, all batches of which are to be withdrawn. No other BSC products are impacted by this withdrawal.

Attached to this letter is a specific listing of products which we have record of shipping to your facility. Please segregate the product immediately and return it to Boston Scientific in accordance with the enclosed instructions.

**AFFECTED PRODUCT LISTING**

UPN	Description	GTIN	Batch
M0068302410	Xenform™ Tissue Repair Matrix - 2cm X 7cm	8714729775133	All batches
M0068302430	Xenform™ Tissue Repair Matrix - 4cm X 7cm	8714729774464	
M0068302450	Xenform™ Tissue Repair Matrix 6cm X 10cm	8714729773764	
M0068302470	Xenform™ Tissue Repair Matrix 8cm x 12cm	8714729774198	
M0068318170	Uphold™ LITE with Capio SLIM Vaginal Support System	8714729839200	
M0068402400	Polyform™ Synthetic Mesh, 10cm x 15cm, box 1	08714729121305	
M0068402410	Polyform™ Synthetic Mesh, 15cm x 20cm, box 1	08714729767015	
M0068318150	Pinnacle™ LITE Pelvic Floor Repair Kit, Posterior	08714729854548	

**Further distribution or use of any remaining product affected by this action should cease immediately.**

**INSTRUCTIONS:**

- 1- **Check your Inventory for the products affected by this Field safety Notice.**
- 2- **Please segregate and do not distribute any of the affected products found in your inventory.**
- 3- **Please notify all your customers that have received affected product of this Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this recall to the medical facility level.
- 4- **Have all affected product returned to your facility** and held in quarantine for reconciliation
- 5- **Please complete the attached Verification Form, even if you do not have any product to return.**
- 6- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer\_Service\_Fax\_Number» on or before **15 May 2019.**
- 7- **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.**

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 high-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 Barlanga  
Quality Department  
Boston Scientific International S.A.

Attachment: Verification Form