Boston Scientific International S.A.
ZAC Paris Nord II/Bât Emerson - 33 rue des Vanesses – 93420 Villepinte
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France
Tel 33 (0)1 48 17 47 00
Fax 33 (0)1 48 17 47 01
www.bostonscientific.com

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

<**Reference: 92682861-FA**> xx April 2021

Urgent Field Safety Notice - Urgent Medical Device Recall
Colpassist™ Vaginal Positioning Device as a component of the Upsylon™ Y Mesh Kit

Dear «Users_Name»,

Boston Scientific Corporation (BSC) is conducting a voluntary removal of all unexpired lots of the Colpassist Vaginal Positioning Device, which is a single use device used as an aid during gynecological procedures. The Colpassist Vaginal Positioning Device is a component of the Upsylon Y Mesh Kit, as detailed in Attachment 1.

BSC has detected through internal testing the potential for pinholes (sterile barrier breach) on the edge of the pouch of the Colpassist Vaginal Positioning Device which are not likely to be detected by the user and may potentially render the device non-sterile. The most serious health risk that potentially could occur from use of a non-sterile Colpassist device is a post-operative vaginal infection of moderate severity that could be managed with medical evaluation and treatment with oral antibiotics in the outpatient setting.

Our records indicate that your facility received some of the concerned product. The **table below (Attachment 1) provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN and Lot/Batch numbers and expiry date. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice**.

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

Product Description	UPN #	GTIN	Lot/Batch #	Expiration Date Range
Upsylon™ Y Mesh Kit with Colpassist™ Vaginal Positioning Device*	M0068318220	08714729848103	See Attachment 1	

***Note:**
This removal does not affect the Upsylon Y Mesh component of the kit, however, since the Colpassist device component is impacted, the entire Upsylon Y Mesh kit must be returned in order to be reimbursed.

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 **7 May 2021**.

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 health 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.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

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Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

Attachment 1 – Product Listing

Product Description	UPN #	GTIN	Kit Lot/Batch #	Colpassist Component Lot/Batch #	Expiration Date Range
Upsylon™ Y Mesh Kit with Colpassist™ Vaginal Positioning Device	M0068318220	08714729848103	C003725	C003699	31 March 2021 – 31 October 2023
			C003726	C003715	
			C003737		
			C003739	C003735	
			C003752		
			C003767	C003750	
			C003778		
			C003782	C003775	
			C003791		
			C003814	C003804	
			C003818		
			C003831	C003813	
			C003845		
			C003846	C003842	
			C003874		
			C003875	C003853	
			C003898		
			C003899	C003887	
			C003921		
			C003942	C003905	
			C003954	C003936	
			C003970	C003950	
			C003988	C003960	
			C003989		
			C003999	C003966	
			C004000		
			C004011	C003986	
			C004012		
			C004031		
			C004033		
			C004032	C003997	
			C004049		
			C004048	C004028	
			C004084		
			C004085	C004041	
			C004086		
			C004097	C004078	
			C004098		
			C004099	C004091	
			C004120	C004107	
			C004132		
			C004143	C004117	
			C004150	C004128	
			C004159		
			C004175	C004136	
			C004176		
			C004196	C004160	
			C004205		
			C004213	C004186	

«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»

Verification Form – Urgent Medical Device Recall

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated xx April 2021.

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° / Serial 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