7th March 2019

FIELD CORRECTIVE ACTION
PRODUCT REMOVAL NOTIFICATION: BM-RAP-19-001-003

BARD Women's Pelvic Organ Prolapse and Stress Urinary Incontinence Mesh Devices

Pelvic Organ Prolapse devices: Alyte® Y-Mesh; Nuvia® SI Prolapse Repair System, Avaulta® Solo Mesh, and Avaulta® Plus Mesh®
Stress Urinary Incontinence devices: Ajust® Single Incision Sling; Ajust® Helical Single Incision Sling; Align Urethral Support System; Align® Trans-Obturator Urethral Support System

Dear Customer,

This letter is to inform you that C. R. Bard, Inc., a wholly owned subsidiary of Becton, Dickinson and Company (BD), is removing its Women's **Pelvic Organ Prolapse and Stress Urinary Incontinence Mesh Devices** from the European market. A list of the impacted product codes can be found in Attachment 1. Our records show that you may have received at least one of the product code / lot number combinations.

BD is initiating a cease in production and distribution of these devices and a removal of these products from hospitals and distribution centers with immediate effect.

This product removal has not resulted from any safety concerns regarding these devices and no additional follow-up activities are required for patients already treated with the devices

Take the Following Actions:

1. Please inspect your inventory, locate any unused device/s as listed in Attachment 1 and quarantine the device/s immediately.

2. Share this product removal notification with all users of the Bard Women's Pelvic Organ Prolapse and Stress Urinary Incontinence Mesh Devices within your facility to ensure awareness.

3. If you have further distributed the devices, please identify those purchasers and notify them at once of this product withdrawal notice and have them return any affected unused devices to your facility.

4. Before returning the devices, mark the outside package as "PRODUCT REMOVAL" and include the following reference number: BM-RAP-19-01-003

5. Once the devices affected by this removal have been removed from your inventory and/or returned to your facility, complete the customer response form.

6. Return the completed customer response form to BDUKFieldAction@bd.com as soon as possible, but no later than the 5th of April 2019.

It should be noted that the removal of any implanted device is not required and no additional follow up activities are required for patients who have any of these devices implanted. A patient information sheet is attached in order to help you answer any patient questions.
Should you have any questions or require assistance in this matter, please contact your local sales specialist or local BD Customer Service Representative.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you

and thank you in advance for helping us to execute this product removal as quickly and effectively as possible.

Yours Sincerely,

William David
Senior Director, EMEA Quality Compliance

Attachment 1: Affected Product List
Attachment 2: Patient Information Sheet

Attachment 1: Affected Product List

Product Codes	Product Description	Device Type	Lot Numbers
BRD100R	Align® Retropubic Urethral Support System with Dilator	Stress Urinary Incontinence	All lots currently in inventory that have not expired
BRD200S	Align® Suprapubic Urethral Support System with Dilator		
BRD300RS	Align® Retropubic-Suprapubic Urethral Support System with Dilator		
BRD400HK	Align® Trans-Obturator (TO) Urethral Support System with Dilator		
BRD500HL	Align® Trans-Obturator (TO) Halo Urethral Support System with Dilator		
BRD600HH	Align® Trans-Obturator (TO) Hook-Halo Urethral Support System with Dilator		
BRD301RS	Align® Retropubic-Suprapubic Urethral Support System with Non-Dilator		
BRD601HH	Align® Trans-Obturator (TO) Hook-Halo Urethral Support System with Non-Dilator		
BRD700SI	Ajust™ Adjustable Single-Incision Sling (Unit Pack)		
BRD705SI	Ajust™ Adjustable Single-Incision Sling (5 Pack)		
BRD800SI	Ajust® Helical (Unit Pack)		
BRD805SI	Ajust® Helical (5 Pack)		
486100	Avaulta® Solo Anterior Support System	Pelvic Organ Prolapse	
486200	Avaulta® Solo Posterior Support System		
486101	Avaulta® Plus Anterior Support System		
486201	Avaulta® Plus Posterior Support System		
Y100	Alyte™ Y-Mesh Graft (Unit Pack)		
Y500	Alyte™ Y-Mesh Graft (5 Pack)		
PF100SI	Nuvia® Single-Incision Anterior Prolapse Repair System		
PF200SI	Nuvia® Single-Incision Posterior Prolapse Repair System		

Attachment 2: Patient Information Sheet

This information is being provided to help answer questions your patients may have about the product discontinuance and with the intent to provide reassurance regarding any devices that are implanted to treat Pelvic Organ Prolapse and Stress Urinary Incontinence which are being removed from the market for business reasons only. Devices of this type are one of several established options surgeons and their patients can chose from to help address their underlying acquired conditions.

- The decision to perform the market removal of this product portfolio was made in light of the fact that there are other competitor products on the market and C. R. Bard's strategic business decision to exit the Pelvic Health business. The devices are not being discontinued because of any safety issue.
- The device discontinuance does not indicate a need to have your device explanted.
- The safety and efficacy for the use of these products, and the associated surgical procedures to implant them, has not changed.
- The various devices met all device specifications and regulatory and quality requirements prior to distribution to customers.
- It is recommended that patients contact their physician with any questions that may arise in regard to these products and the associated procedures.
- It is recommended that patients continue with their routine check-ups and follow-up care as recommended by their physician.
- There is no need to take additional action if patients are satisfied with their surgical outcomes and are not having complications or symptoms. There is no need to have the devices explanted.
- Patients are invited to notify their health care provider if they believe they may have complications or symptoms, including but not limited to persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sexual activities or else at their follow-up appointment.
- Patients should raise any questions that may have to their physician,

Customer Response Form – BM-RAP-19-01-003

Bard Women's Pelvic Organ Prolapse and Stress Urinary Incontinence Mesh Devices

Ajust® Single Incision Sling; Ajust® Helical Single Incision Sling; Align® Urethral Support System; Align® Trans-Obturator Urethral Support System; Alyte® Y-Mesh; Nuvia® SI Prolapse Repair System, Avaulta® Solo Mesh, and Avaulta® Plus Mesh

Fill out and return this form to BD at BDUKFieldAction@bd.com.

Tick the appropriate box below

☐ We do not have any of the affected product as listed in Attachment 1 in our possession

OR

☐ We have the following units of the affected product as listed in Attachment 1 in our possession and I confirm that the units have been quarantined to be returned to BD *(Please complete the table with the number of units)*

Product Reference (catalogue number)	Lot Number	Quantity of Units on hand

By completing the information below you confirm that this notice has been read, understood and that all recommended actions have been implemented as required.

Please PRINT Your Contact Information and fill form out completely	
Name	
Title	
Name of Account / Hospital	
Contact Phone Number	
Date	
Signature	

This form must be returned to BD before this action can be considered closed for your account.