



Medical Device Alert

MDA/2019/014

Issued: 07 March 2019 at 11:00

Valid until: March 2020

All Bard urogynaecological mesh – voluntary product withdrawal, implanted devices do not need to be removed

Summary

Manufactured by C.R. Bard (Becton, Dickinson and Company (BD)) – surgical mesh for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) is being withdrawn from hospitals and distribution centres.

Action

If you work in procurement or are a healthcare professional:

- Identify and quarantine affected, unused devices listed in the attached manufacturer notice.
- Ensure, in cooperation with implanting surgeons, that suitable alternative devices are available.
- Follow the actions listed in the attached manufacturer notice.
- Report adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: [England](#), [Scotland](#), [Northern Ireland](#), [Wales](#). You should also report directly to manufacturers if your local or national systems do not.

If you are a patient and have this device implanted:

- You don't need to have the device removed or have any extra follow-up checks.
- Read the attached manufacturer notice.
- If you have any concerns about your implanted device, contact your GP or healthcare professional.
- Report any problems you have with the mesh to the [Yellow Card Scheme](#) in England or the appropriate authority in [Scotland](#), [Northern Ireland](#) and [Wales](#).

Action by

All healthcare professionals who use these devices and staff responsible for the stock and purchasing of these devices.

Deadlines for actions

Actions underway: 14 March 2019

Actions complete: 21 March 2019

Device details

All urogynaecological mesh products for SUI and POP manufactured by C.R. Bard. See the attached manufacturer notice for a full table of devices affected.

Problem / background

Bard has chosen to stop production and distribution of these devices. They are removing all urogynaecological mesh products from hospitals and distribution centres.

Bard has taken the decision to stop production of these devices as part of its business strategy. We understand from Bard's explanation that they are stopping production rather than continuing to invest in clinical data to support additional EU requirements. Therefore, implanted devices don't need to be removed and no additional follow-up is required for patients implanted with these devices.

We have continued to work closely with NHS England, NICE and professional bodies, and we are all committed to helping address the serious concerns raised by women who have experienced complications with mesh devices.

We encourage anyone – patient, carer or healthcare professional – who is aware of a complication after a medical device is implanted, to report to us via the [Yellow Card scheme](#), regardless of how long ago the implant was inserted.

Manufacturer contacts

C.R. Bard

Email: BDUKFieldAction@bd.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Day surgery units
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Medical directors
- Nursing executive directors
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Operating department practitioners
- Purchasing managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General practitioners (for information only)
- General practice managers
- General practice nurses

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/014** or **2019/002/025/291/005**.

Technical aspects

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the [Yellow Card reporting page](#)

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health, Social Services and Public Safety

Tel: 0208 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the [forms on the website](#).

Alerts in Northern Ireland are distributed via the [NICAS system](#).

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.irc@nhs.net

To report an adverse incident involving a medical device in Scotland, [email IRIC](#) to request a webform account.

For more information, or if you can't access the webform, visit the website: [how to report an adverse incident](#)

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the [Yellow Card reporting page](#) and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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Addressees may take copies for distribution within their own organisations



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,

A handwritten signature in blue ink that reads "William David".

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		
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 choose 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.