URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

November 6, 2024

Dear Valued McKesson Customer:

Cypress Medical Products, LLC has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Field Safety Notice regarding one lot of their McKesson Reinforced Aquafiber manufactured by Advanced Medical Solutions LTD (AMS). This notice has been issued because minor missing patches of Polyethylene have been detected on the primary packaging pouches. The defect on these pouches could compromise the device's ability to maintain a sterile barrier. Affected product first shipped May 23, 2024.

This Urgent Medical Device Field Safety Notice is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For clinical inquiries, please contact Advanced Medical Solutions Ltd via email at Customer.Support@admedsol.com.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table below for a list of affected item(s) and lot number(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)
883265	3562	DRESSING, CALCIUM ALGINATE SHEET 4"X4.75" (10/BX 1	W00070426

McKesson Customer Instructions:

1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed above. If you have no product matching the affected item(s) and lot number(s), no further action is needed.

2.) A copy of the Urgent Medical Device Field Safety Notice from Cypress Medical Products, LLC and Advanced Medical Solutions Ltd have been included for reference.

3.) Regardless of whether if you have affected product, complete the Advanced Medical Solutions Ltd Customer Reply Form and Certificate of Destruction, if applicable, included with this notification and submit it to via email to Customer.Support@admedsol.com. Please indicate that you are a McKesson Medical-Surgical customer on the Reply Form.

4.) Once Advanced Medical Solutions Ltd receives your Customer Reply Form and Certificate of Destruction, replacement product will be issued to you.

5.) Please dispose of any affected product in your possession in accordance with your institution's policies and procedures.

6.) If you have further distributed any of the item(s) referenced in this notification, provide your Retail level accounts with a copy of this notification.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

Cypress Medical Products, LLC
9954 Mayland Drive, Suite 4000
Richmond, VA 23233
(800)334-3646

CYPRESS MEDICAL PRODUCTS

0005584

URGENT: Medical Device Field Safety Notice

October 30, 2024

Dear Distributor:

Advanced Medical Solutions Ltd (AMS) has notified Cypress Medical Products, LLC of an **Urgent Medical Device Field Safety Notice** for MMS Brand REINFORCED AQUAFIBER 4x4.75", MFR# 3562, LOT W00070426. Minor missing patches of Polyethylene have been detected on the primary packaging pouches.

Hazard Involved: The defect on these pouches could compromise the device's ability to maintain a sterile barrier.

Please refer to the attached AMS Field Corrective Action – Field Notice 10-01-2024-001-FSCA for further details.

The impacted products and lot numbers are listed below:

McKesson Part #	Description	Lot
3562	McKesson REINFORCED AQUAFIBER 4x4.75"	W00070426

****Please note: This is **not** a recall. Product returns will not be accepted.****

The manufacturer has determined that the impacted medical devices should be destroyed. *Please review and implement the actions listed below.*

Action to be Taken by the Distributor:

- Inspect internal inventory for the aforementioned packaging defect and quarantine all affected product pending safe destruction.
- ~~As soon as possible but no later than 14 days after receipt of this FSN, please complete the attached **APPENDIX 1 – Distributor/Logistic Centers Form** and return to AMS either by post or by email to the addresses stated on the form~~.
- Complete the attached **APPENDIX 3 – Certificate of Destruction Form** and return to AMS either by post of by email to the addresses stated on the form.
- Distribute this FSN to all affected end-user customers/Healthcare facilities alongside the attached **APPENDIX 2 – Customer Reply Form and APPENDIX 3 – Certificate of Destruction**. Please advise customers to execute actions.

This FSN does not need to be communicated to patients. There is no action to take with patients.

Defective product will be replaced free of charge upon receipt of **APPENDIX 3, Certificate of Destruction**. If this is not preferred, please contact AMS customer services via phone (+44 1606 545617) or email (Customer.Support@admedsol.com).

Adverse reactions experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program online at www.fda.gov/medwatch/reprot/htm.

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Premier Park, 33 Road One,
Winsford Industrial Estate,
Winsford, Cheshire, CW7 3RT, UK
Tel: +44 (0) 1606 863500 Fax: +44 (0) 1606 863600
Web: www.admedsol.com
Registered in England 2666957 VAT No. GB 636 5551 27

Advanced Medical Solutions Ltd

Field Corrective Action - Field Notice
10-01-2024-001-FSCA

Date Issued: 11th October 2024

Affected Product ("Product"):

Product name: **Silvercel Hydro Alginate, Silvercel Non-Adherent, Tegaderm Alginate, ActivHeal Alginate, ActivHeal Aquafibre, ActivHeal Non-Adhesive Foam, ActivHeal Non Adhesive Tracheostomy, ActivHeal PHMB Foam Non-Adhesive, ActivHeal Raponicel Ultra, Biatain Alginate, Hyalo 4 High Gelling Fibre, Calcicare Reinforced Alginate, Reinforced Aquafibre, Nurocel Extra, Maxorb Extra**

Product code: *As below*

SRN: GB-MF-000009715

Dear valued customer

Advanced Medical Solutions Limited ("AMS") has initiated a voluntary recall for the products listed above. The affected lots are detailed in the table below:

Reference	Lot Number	Expiration Date
371569980	W00068269	11-Nov-2026
371079980	W00068634	28-Nov-2026
CAD7011	W00068666	30-Nov-2026
10010227	W00068967	28-Jan-2027
10009115	W00069144	28-Jan-2027
900202	W00069222	31-Jan-2027
800202	W00069223	31-Jan-2027
10007432	W00069225	28-Jan-2029
10009145	W00069226	28-Jan-2027
371079980	W00069434	09-Feb-2027
10009118	W00069459	28-Feb-2027
10009147	W00069623	28-Feb-2027
900202	W00069627	31-Jan-2027
10009114	W00069687	28-Mar-2027
10009115	W00069688	28-Mar-2027
529937R	W00070134	02-Apr-2027

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CAD011	W00070266	31-Mar-2027
10009115	W00070355	28-Apr-2027
10009118	W00070356	28-Apr-2027
3562	W00070426	22-Apr-2027
9021348	W00070461	28-Apr-2026
9040615	W00070513	28-Jun-2027
9021348	W00070519	28-Apr-2026
371079980	W00070520	26-Apr-2027
371569980	W00070556	26-Apr-2027
CAD011	W00070657	30-Apr-2027
90112	W00070779	14-May-2029
2010	W00070788	21-May-2027
MSC7044EP	W00070789	21-May-2027
MSC7048EP	W00070988	29-May-2027
90110	W00070995	23-May-2029
10009118	W00070999	28-May-2027
HPD15X15	W00071060	30-Jun-2027
10009118	W00071065	28-Jun-2027
10007432	W00071075	28-Jun-2029
HPD10X10	W00071153	30-Jun-2027
CAD011	W00071172	31-May-2027
CAD050	W00071173	31-May-2027
10007431	W00071239	28-Jun-2029
10009146	W00071240	28-Jun-2027
10009113	W00071248	28-Jun-2027
10009118	W00071252	28-Jun-2027
10007431	W00071284	28-Jun-2029
10009118	W00071289	28-Jun-2027

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4. Please immediately distribute this FSN to all affected end user customers/Healthcare facilities alongside the attached **'APPENDIX 2 - CUSTOMER REPLY FORM'** and **'APPENDIX 3 - CERTIFICATE OF DESTRUCTION'**. Please advise them to execute the actions and collect the forms from your customers.
5. **END USERS** – Please ensure product is inspected at point of care in line with the aforementioned packaging defect and execute actions in accordance with this Notice
6. The FSN does not need to be communicated to patients. There is no action to take with patients.
7. Defect product will be replaced free of charge upon receipt of certificate of destruction (Appendix 3) . If this is not preferred, please contact AMS customer services.
8. Customer Services Contact Number: +44 1606 545617
   Email: Customer.Support@admedsol.com

ALL OTHER CUSTOMERS
(Any organisation that buys Product from AMS for end use)

1. Immediately inspect your internal inventory for the aforementioned packaging defect and quarantine all affected Product pending safe destruction.
2. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached **'APPENDIX 2 - CUSTOMER REPLY FORM'** and return it to AMS either by post or by email to the addresses stated on the form.
3. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached **'APPENDIX 3 - CERTIFICATE OF DESTRUCTIONFORM'** and return it to AMS either by post or by email to the addresses stated on the form.
4. **END USERS** – Please ensure product is inspected at point of care in line with the aforementioned packaging defect and execute actions in accordance with this Notice
5. The FSN does not need to be communicated to patients. There is no action to take with patients.
6. Defect product will be replaced free of charge upon receipt of certificate of destruction (Appendix 3) . If this is not preferred, please contact AMS customer services.
7. Customer Services Contact Number: +44 1606 545617
   Email: Customer.Support@admedsol.com

Contacts

We sincerely apologise for any inconvenience caused by this FSN, patient safety and compliance is very important to us. In the meantime, if you have any other questions related to this FSN please contact Customer.Support@admedsol.com.

The undersigned confirms this FSN will be notified to the appropriate Competent Authorities.

Enclosed forms

Appendix 1. Field Safety Notice: DISTRIBUTOR / LOGISTIC CENTRES FORM
Appendix 2. Field Safety Notice: CUSTOMER REPLY FORM
Appendix 3. CERTIFICATE OF DESTRUCTION

Yours faithfully,

Signed by James Bartlett
James Bartlett Approve this document
11-Oct-2021 15:08 BST

James Bartlett
Regulatory and Clinical Affairs Director
For and on behalf of Advanced Medical Solutions Limited

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Advanced Medical Solutions Ltd
Product Issue

AMS has become aware of a defect on primary packaging pouches, in which minor missing patches of Polyethylene have been detected. The defect on these pouches could compromise the device's ability to maintain a sterile barrier. In addition, patches of burnt or cracked polyethylene have been identified on the inside face of the primary packaging. The left and central images (FIG 1 & FIG 2) below display examples of the polyethylene burn, while the right image (FIG 3) highlights the area of potential sterility loss due to missing polyethylene, shown by a variation in colour

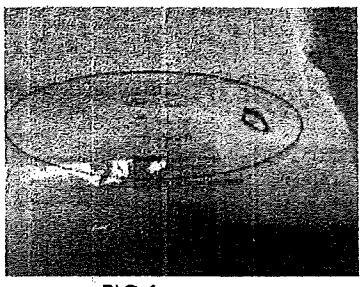
FIG 1

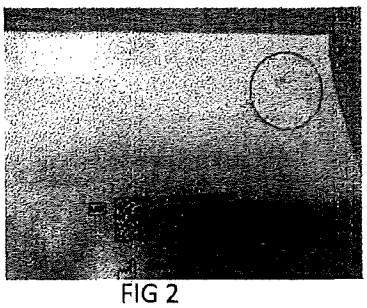
FIG 2

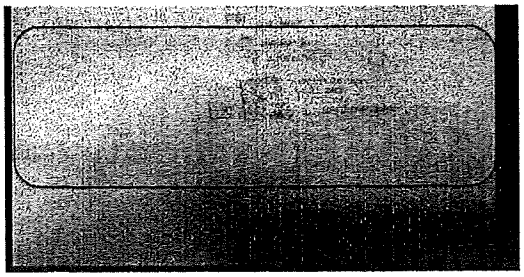
FIG 3

Potential Risk

A device with compromised sterility carries a worst-case potential harm to cause a major infection to the patient. The marks of burnt lacquer on the inside face of the pouch are highly detectable by the end user. The areas of the pouch that contain missing patches of lacquer can be readily detected with guidance. The areas that the polymer application phase did not fully coat the surface can be seen by the presence of a matte finish, as opposed to the expected high gloss finish. AMS has determined that any potentially affected Product in the market presents a low probability of risk to a patient's health. To date there have been no complaints or adverse events reported associated with this defect.

Required actions regarding the use of the Product

Our records indicate that you have received stock of the Product and you are therefore affected by this action.

Where Product has already been used in patients under a three-month time period, patients should be monitored for symptoms during routine clinical follow up. If you are aware of any patient experiencing symptoms related to this FSN it should be reported to AMS straight away.

All Distributors and Customers must ensure that the FSN is sent to treating clinicians at facilities within 24 hours of receipt of this Notice.

We kindly request that you read this Field Safety Notice ("FSN") carefully and complete the following actions within 14 days of receipt of this Notice:

DISTRIBUTOR / LOGISTIC CENTRES
(Any organisation that buys Product from AMS and then provides them to end users or to sub-distributors)

1. Immediately inspect your internal inventory for the aforementioned packaging defect and quarantine all affected Product pending safe destruction.
2. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached '**APPENDIX 1 - DISTRIBUTOR / LOGISTIC CENTRES FORM**' and return it to AMS either by post or by email to the addresses stated on the form.
3. As soon as possible, and no later than 14 days after receipt of this FSN, please complete the attached '**APPENDIX 3 - CERTIFICATE OF DESTRUCTION FORM**' and return it to AMS either by post or by email to the

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Appendix 2. Field Safety Notice: CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	10-01-2024-001-FSCA
FSN Date	01 October 2024
Refer to Field Safety Notice for further product details	

2. Customer Details	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the FSN	
☐	I have checked my Product stock and quarantined affected inventory	
☐	I have destroyed affected Product– enter number destroyed and date complete	Please provide a Certificate of Destruction as attached:
☐	I confirm any Product not destroyed has already been used	
	Print Name:	
	Signature:	
	Date :	

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Appendix 3 - CERTIFICATE OF DESTRUCTION

In respect of the Products subject to 10-01-2024-001-FSCA, and in regard to the provided FSN; I hereby confirm that I have destroyed the following items and quantities as instructed:

Device Name	REF	LOT Number	Qty (carton/boxes)

Name: _____

Institution/Company Name: _____

Signature: _____

Date: _____

This form is to be returned **no later than 14 days after receipt of this FSN**.

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4. Return acknowledgement to Sender If you are not a direct customer of AMS , please return this form to your distributor.	
Email	
Customer Helpline	
Postal Address	
Deadline for returning the Customer reply form	This form is to be returned no later than 14 days after receipt of this FSN.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Cypress Medical Products, LLC
9954 Mayland Drive, Suite 4000
Richmond, VA 23233
(800)334-3646

Please contact globalsourcingqa@McKesson.com with any questions or concerns regarding this notification.

We appreciate your immediate attention and apologize for any inconvenience caused by this matter.

Sincerely,

Jill Early
Quality Manager
Cypress Medical Products, LLC
Jill.Early@McKesson.com

Signed by:
Jill Early
Signer Name: Jill Early
Signing Reason: I am the author of this document
Signing Time: Oct 30, 2024 | 19:01 CET
37878D3F5599449E891DAF4B376CBEA2