



Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

November 1, 2024

MEDICAL DEVICE RECALL

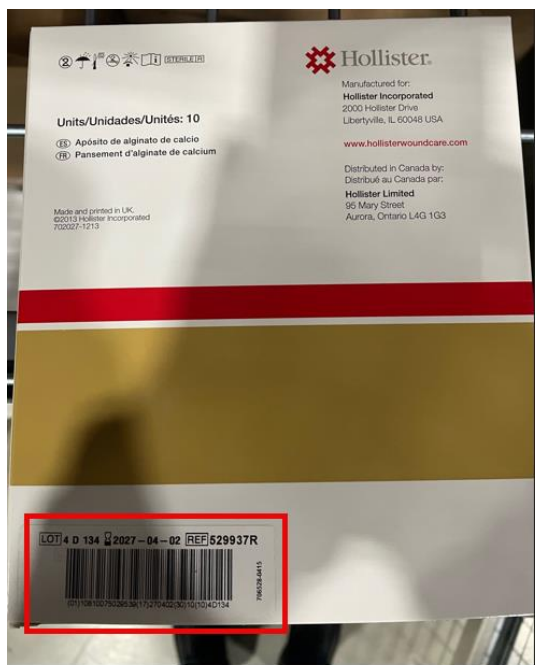
CalciCare™ Calcium Alginate Dressing

Dear Valued Business Partner/Customer,

In order to best serve the needs of our customers, Hollister Incorporated, the distributor, is forwarding a voluntarily recall from Advanced Medical Solutions, Ltd. (AMS), the manufacturer of CalciCare Calcium Alginate Dressing 4" x 4.75". Our records indicate that you have received stock of the product listed below and you are therefore affected by this action.

AMS	Hollister
CalciCare™ Calcium Alginate Dressing 4" x 4.75" Catalog number 9937 LOT number W00070134	CalciCare™ Calcium Alginate Dressing 4" x 4.75" Hollister Catalog number 529937R Hollister LOT number 4D134

The photos below are what the box of product with the lot number looks like:



We are requesting that you follow the steps below:

We kindly request that you read the AMS Medical Device Recall notice (Field Safety Notice "FSN") carefully and complete the actions listed on the included AMS document within 14 days of receipt of this Notice:

DISTRIBUTOR / LOGISTIC CENTERS

(Any organization that buys Product from Hollister and then provides them to end users or to sub-distributors)

1. Search inventory for SKU 529937R with lot number 4D134

The SKU and lot number information are printed on the product label that is located on the box of product. Please refer to the preceding Images and note the red box around the SKU and lot location:

2. As soon as possible, and no later than 14 days after receipt of this Medical Device Recall notice, please complete the attached '**Appendix 1 - DISTRIBUTOR / LOGISTIC CENTER FORM**' or '**Appendix 2 – CUSTOMER REPLY FORM**' and '**Appendix 3 – CERTIFICATE OF DESTRUCTION**' and return it to **Hollister** at the following email address - ComplaintCommunication@Hollister.com even if you do not have affected product in your possession.

Product Credit requests

1. Contact Hollister Incorporated for product credit requests.
 - US dealers, distributors, institutions and pharmacies call 1-800-323-4060 option 1.
 - US Consumers or healthcare professionals, please call 1-888-808-7456.

We apologize for the inconvenience which this recall will undoubtedly cause. Thank you again for being our valued business partner and for your understanding regarding this matter.

Sincerely,



Linda Wisowaty BSN, RN
Lead Post Market Surveillance Specialist.



Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Customer Frequently Asked Questions (FAQ) CalciCare Calcium Alginate Dressing

1. What product is impacted for this recall?

Hollister Product
CalciCare Calcium Alginate Dressing 529937R - Lot number 4D134

2. How do I identify the affected product?

The SKU and lot number information are printed on the product box and label that is located on the box. Match this information to the information above to see if your product is affected.

3. What is the process to receive credit?

For consumers or health care professionals, contact Hollister in the US at 1-888-808-7456
For dealers, distributors, institutions and pharmacies, contact Hollister in the US at 1-800-323-4060 option 1 or Hollisterteam@hollister.com.

4. Do I need to send the affected product back to Hollister?

No. If you have any affected product, we would like you to destroy the product and return the certificate of discretion form.

5. What if I don't have affected product or I have already disposed of it?

Even if you don't have affected product, please complete, and return the response form. This will allow us to quickly and easily confirm that there is no affected product in your possession. Return response form to ComplaintCommunication@Hollister.com.

6. Was anyone injured using the affected product?

Neither AMS or Hollister have received any complaints reporting an injury with the use of this product affected by this recall.

7. Who do I contact for more assistance?

Please contact one of the following Hollister Incorporated departments:
US Hollister Customer Service:
Consumer or healthcare professionals 1-888-808-7456
Dealers, distributors, institutions and pharmacies 1-800-323-4060 option 1
Hollister Quality: ComplaintCommunication@Hollister.com



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, Caldicare 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



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



Advanced Medical Solutions Ltd

Product Issue

Advanced Medical Solutions Limited
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

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

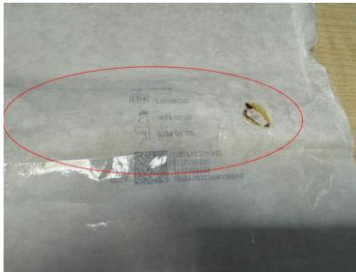


FIG 1



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 addresses stated on the form.



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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
 | I approve this document
11-Oct-2024 | 15:04 BST

James Bartlett

Regulatory and Clinical Affairs Director

For and on behalf of Advanced Medical Solutions Limited



Advanced Medical Solutions Ltd

Advanced Medical Solutions Limited
Premier Park, 33 Road One,
Winsford Industrial Estate,
Winsford, Cheshire, CW7 3RT, UK
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Appendix 1. Field Safety Notice: DISTRIBUTOR / LOGISTIC CENTRES FORM

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

2. Return Acknowledgement to sender	
Email	Customer.Support@admedsol.com
Customer Service	01606 545617
Postal Address	Customer Services Advanced Medical Solutions Limited Premier Park, 33 Road One, Winsford Industrial Estate, Winsford, Cheshire CW7 3RT
Deadline for returning the Distributor reply form	This form is to be returned no later than 14 days after receipt of this Field Notice

3. Distributor/Importer Details	
Company Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	



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4. Distributors/Importers (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	Date Quarantined:
☐	I have identified customers that received or may have received this Product	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have destroyed affected Product – enter number destroyed and date complete	Please provide a Certificate of Destruction as attached:
☐	Neither I nor any of my customers has any affected Product in inventory	
Print Name (Distributor name):		
Signature (Distributor signature):		
Date :		

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.



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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 :		



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.



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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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Winsford, Cheshire, CW7 3RT, UK
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15 October 2024

Dear Customer,

Reference: Field Safety Notice: 10-01-2024-001-FSCA

We are writing to advise you that Advanced Medical Solutions Limited ("AMS") has issued a Field Safety Notice ("FSN") relating to the following dressings/wound care products that have been distributed to you.

Product	REF	LOT
CALCICARE 4X4.75"	9937	W00070134

We have unfortunately detected non-conforming product which is an isolated incident. The root cause has been identified and corrective actions implemented, future orders will not be impacted.

We have put patient safety first and to support this we are asking, as part of the Field Safety Corrective Action (FSCA), you inspect the primary packaging for burn marks as per the instructions in the FSN. Following inspection, please follow the further instructions documented in the notice.

If you do find affected product, AMS requests that you dispose of the item(s) in accordance with the FSN.

Can you please forward this FSN immediately to the most appropriate person in your organization if not yourself, and perform the actions requested as we require the actions to be completed within 14 days of your receipt of this Notice.

AMS sincerely apologises for the difficulty this situation may cause your facility. Our customer service team will automatically replace destroyed product free of charge upon receipt of your completed Certificate of Destruction.

Thank you for your understanding in this matter.

Kind Regards,

James Bartlett

Regulatory and Clinical Director