CLASS II - Urgent Medical Device Recall

TGA Recall Reference number – RC-2024-RN-00965-1

SILVERCEL Non-Adherent Hydro-Alginate Antimicrobial Dressing/Packing with Silver - Dressing, highly-absorbent, hydrophilic gel-forming, antimicrobial

Description	ARTG	REF	LOT	SKU
SILVERCEL NON-ADHERENT 11X11CM	175609	CAD7011	68666V002	70001705873

November 1, 2024

Dear Distributor:

Solventum, formerly 3M Health Care, values the care of our patients and the quality of our products. KCI Medical Australia Pty Ltd (herein referred to as “Solventum”) as the Sponsor and following agreement with the Therapeutic Goods Administration (TGA), is conducting a CLASS II - Urgent Medical Device Recall of the above SILVERCEL Non-Adherent Hydro-Alginate Antimicrobial Dressing/Packing with Silver - Dressing, highly-absorbent, hydrophilic gel-forming, antimicrobial (“Product”). The legal manufacturer of the Product is Advanced Medical Solutions Limited (“AMS”).

Our records indicate that you have been supplied with the Product.

What is the problem?

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

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.

This class ll – urgent medical device recall does not affect any other batches of SILVERCEL Non-Adherent Hydro-Alginate Antimicrobial Dressing or any other AMS/Solventum products.

This LOT 68666V002 has been distributed to distributors and hospitals since April 2024.

- 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 Recall Notice it should be reported to Solventum straight away.

- All Distributors and Customers must ensure that this notice is sent to treating clinicians at facilities immediately upon receipt of this Notice.

We kindly request that you read this letter carefully and complete the following actions:

Action to be taken by all Distributors:

1. Inspect your stock immediately and quarantine affected stock 68666V002 on hand to prevent further distribution.
2. Ensure all your internal and external customers are informed about this corrective action.
3. Send this letter and attachments to all affected customers.
4. Please inform us if you supplied the affected items to customers outside your home country to ensure completeness of competent authority notification.
5. Please discard all remaining affected product listed above per facility procedures.
6. Complete and return immediately by e-mail to anzfieldaction@solventum.com the enclosed Appendix 1 - DISTRIBUTOR Response form and Appendix 3 - CERTIFICATE OF DESTRUCTION form **even if you do not have any affected stock** so we can reconcile this recall.
7. With receipt of this certificate of destruction, Solventum will arrange for compensation, any issues please contact Solventum Customer Service by phone on 1300 363 878.

Action to be taken by all Customers:

1. Inspect your stock immediately and quarantine affected stock 68666V002 on hand to prevent further use.
2. Please discard all remaining affected product listed above per facility procedures.
3. Complete and return immediately by e-mail to anzfieldaction@solventum.com the enclosed Appendix 2 - CUSTOMER RESPONSE form and Appendix 3 - CERTIFICATE OF DESTRUCTION form **even if you do not have any affected stock** so we can reconcile this recall.
4. With receipt of this certificate of destruction, Solventum will arrange for compensation, any issues please contact Solventum Customer Service by phone on 1300 363 878.

Place this letter in a prominent position for at least one month.

Solventum takes the quality of our products seriously, and we strive to meet or exceed our customers' expectations. We apologise for any inconvenience and greatly appreciate your understanding as we are taking action to ensure correct product performance.

If you have any questions, please contact your local Solventum representative.

Sincerely,

Leanne Hartge
Head of Regulatory Affairs and Compliance, ANZ.

Appendix 1. Distributor Response Letter

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ARTG 175609, Catalogue code CAD7011, Batch 68666V002

1. Field Safety Notice (FSN) information	
TGA Recall Reference Number	RC-2024-RN-00965-1
Recall Date	1st of November 2024

2. Return Acknowledgement to sender	
Email	anzfieldaction@solventum.com
Deadline for returning the Distributor reply form	This form is to be returned immediately

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

4. Distributors (Tick all that apply)		
☐	I confirm the receipt, the reading and understanding of the letter	
☐	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 letter	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 :		

PLEASE RETURN YOUR COMPLETED FORM TO anzfieldaction@solventum.com.

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Appendix 2. Customer Response Letter

CLASS II - Urgent Medical Device Recall

Please complete this form *even if you do not have any affected stock.*

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ARTG 175609, Catalogue code CAD7011, Batch 68666V002

Please check the box below:

☐ We have read the SILVERCEL Non-Adherent Hydro-Alginate Antimicrobial Dressing Class ll Urgent Medical Device Recall Notice and we understand the communication and the required actions.

On behalf of this organisation I acknowledge receipt of the above Recall notice dated 1st of November 2024 relating to the above product.

FROM:

Organisation	
Position	
Name	
Email or fax no.	
Telephone no.	
Date	
Signature	

Affected Stock

If you have no affected stock, tick this box: ☐

If you have affected stock, please complete the stock details table below.

Product	**Batch/Lot/Date**	**Quantity of stock received**	**Quantity of unused stock subject to recall** **(currently in quarantine)**
Total affected product			
Other Relevant Details:			

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ **No**

☐ **Yes I/we will forward all the recall information to the suppliers/distributors/customers**

OR

☐ **Yes (please supply names and contact information of the organisations)**

Return completed forms by fax or email to:

Name	
Position	
Organisation	
Address	
Email	
Subject of email	**[Type of action] of [Product details and description including batch/lot details]**
Fax no.	
Telephone no.	

PLEASE RETURN YOUR COMPLETED FORM TO anzfieldaction@solventum.com.

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Appendix 3 - CERTIFICATE OF DESTRUCTION

In respect of the Products subject to TGA Recall– RC-2024-RN-00965-1, 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: _____

PLEASE RETURN YOUR COMPLETED FORM TO anzfieldaction@solventum.com.