

Convatec Reference: TW-1832110

FSCA Notice Type: Original/New

Date: Feb-2024

URGENT: VOLUNTARY FIELD SAFETY CORRECTIVE ACTION

CarboFlex™ Dressings - 8x15cm & 15x20cm

To: Affected Consignees,

Convatec Inc is conducting a Voluntary Medical Device Field Safety Corrective Action (removal) for specific lots and dressing sizes of CarboFlex™ due to routine testing not meeting Convatec's product sterility assurance level of $\leq 10^{-6}$. To date, no complaints or adverse events have been reported related to this issue.

The associated hazard and potential risk to the end-user would be moderate due to potential infection which could result in medical intervention however, the probability of occurrence is remote.

Description	Product Item Number	Lot Number	UDI Primary Pack
CARBOFLEX DRS WT 8X15CM	ICC 403203	3J02333 3L04810	Refer to Appendix 2
CARBOFLEX DRS WT 15X20CM	ICC 403204	3J00675 3J02320 3J02332 3L04811 4A00343	Refer to Appendix 2

Note – The information above illustrates all products/lots affected. Country specific details are within Appendix 2



Our records indicate that you may have received the affected units which were distributed between 18-Dec-2023 and 01-Feb-2024.

Immediately examine your inventory and quarantine product subject to this communication. In addition, if you have distributed this product further, please identify **your customers**, and notify them at once of this product Field Safety Corrective Action (FSCA). The notification to your customers may be enhanced by including a copy of this letter.

This FSCA should be carried out at the distributors, wholesalers, retailers, and end-user level. Your assistance is required to prevent further distribution and inconvenience to customers. Please follow the **“Your Responsibilities”** section and ensure to complete and return the enclosed response form – **Appendix 1** within 30 calendar days of receipt.

TRANSMISSION OF THIS COMMUNICATION

- Please ensure this communication is shared with the correct department, function, or individual within the organisation i.e., Compliance Team, Regulatory Team, Recall Team etc.
- This notice needs to be disseminated on to all who need to be aware within your organisation or to any organisation where the potentially affected devices have been distributed.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.
- Please report all device-related incidents to the manufacturer, distributor, or local representative, as this provides important feedback.

Any further questions please contact Convatec Recall Coordinator >> Rebecca Thomas – rebecca.thomas@convatec.com

Thank you for your assistance and, **Convatec regret any inconvenience caused by this action.**

Sincerely,

Head of IC/AWC – Regulatory Affairs
Steeve Lamvohee


Sincerely,

Site Quality Director
Stine Corfitz

(Authorised Representative)

DocuSigned by:

Signer Name: Steeve Lamvohee
Signing Reason: I approve this document
Signing Time: Feb 29, 2024 | 10:07:34 AM GMT
79126EF62CD04B7AA0479B4D5AA7AE98

DocuSigned by:

Signer Name: Stine Corfitz
Signing Reason: I approve this document
Signing Time: Feb 29, 2024 | 3:25:05 PM GMT
0C51F81E9300405887306F1A1FC666B9

YOUR RESPONSIBILITIES

DISTRIBUTORS, WHOLESALERS, RETAILERS, END-USER/CONSUMER LEVEL

1. Review this notification and ensure that all relevant stakeholders are aware of this FSCA communication.
2. Immediately locate and quarantine affected product in your inventory.
3. Complete **Appendix 1** and return to Convatec within 30 calendar days of receipt.
4. A review of the information you provide in accordance with **Appendix 1** will be completed.
5. If the information from Step 4 is satisfactory, formal authorization from a Convatec Representative will be provided to proceed with product destruction.
6. Convatec will provide you with a Certificate of Destruction (COD) to complete.
 - a. If you have your own business Certificate of Destruction (COD) that you are required to use, Convatec will accept this documentation, however, please ensure all relevant information pertaining to this FSCA is included for traceability.
7. Immediately destroy all affected product and provide Convatec with a signed Certificate of Destruction (COD) as evidence to support reconciliation.
8. Your account will be credited for all destroyed product upon receipt of a signed form as per **Appendix 1** and a Certificate of Destruction (COD). Please ensure your account number is correctly identified on **Appendix 1**.
9. If you are in receipt of this communication and are still unsure how to proceed, please contact Convatec via de.kundenservice@convatec.com or 0800 162 4381.

APPENDIX 1

RESPONSE FORM

Immediately complete the response form.

If you have no product a completed response form is still required.

Please return the completed form via the instructions below.

Issue Date: Feb-24

CVT Ref: TW-1832110

Original / New Notice: X

Revised Notice: N/A

Revision Number: Rev.1

Invoice #	Sales Order #	Product Code	SAP Code	LOT#	Quantity Delivered

Consignee Account No:		
Consignee Business Name:		
Consignee Address:		
<input type="checkbox"/>	I confirm receipt, understanding and acknowledgement of this notification	
<input type="checkbox"/>	I have checked my inventory and I have product on hand	QTY
<input type="checkbox"/>	I have checked my inventory, quarantined, and disposed of affected inventory	
<input type="checkbox"/>	I have attached a Certificate of Destruction (COD) as requested evidence	
<input type="checkbox"/>	I have identified customers that received or may have received affected product	
<input type="checkbox"/>	I have informed the identified customers of this notification	Date Sent (DD/MMM/YYYY)

NOTE: If the statements listed within the table are not applicable, please mark as N/A

APPENDIX 1**RESPONSE FORM**

Immediately complete the response form.

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Please return the completed form via the instructions below.

Issue Date: Feb-24**CVT Ref: TW-1832110****Original / New Notice: X****Revised Notice: N/A****Revision Number: Rev.1**

FSCA NOTICE ACKNOWLEDGEMENT

NAME	
POSITION	
SIGNATURE	
DATE (DD/MMM/YYYY)	

A signed Response Form (Appendix 1) should be returned to your local CVT Customer Services Representative in the same manner you received the notification.

Alternatively correspondence can be provided via email to the Convatec Recall Coordinator rebecca.thomas@convatec.com

APPENDIX 2

Country	Product SAP Code	Product ICC Code	Lot Number	Primary UDI	Date of Manufacture	Expiry Date/BBD
Switzerland	1226671 1226571	403204 403203	3J02332 3L04810 3L04811	00768455173129	03-Oct-2023 04-Dec-2023 12-Dec-2023	01-Sep-2028 01-Nov-2028

*****Note: This is product information distributed in Switzerland market only*****