Convatec Reference: TW- 1943643
Notice Type: Original/New

Date: Jul-2024

URGENT: FIELD SAFETY NOTICE
Medical Device Recall
Kaltostat® Wound Dressings & Rope

ATTENTION: Affected Consignees,

Convatec Ltd is conducting a Voluntary Field Safety Corrective Action (removal) for specific lots and sizes of Kaltostat® Wound Dressings & Rope due to routine testing not meeting Convatec's product sterility assurance level. To date, no complaints or adverse events have 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	ICC Code	SAP Code	Lot Number	UDI Primary Pack
KALTOSTAT DRS WT 5X5CM (1X10PK) STER	168210	1203783	4E05238	00768455122783
KALTOSTAT DRS WT 7.5X12CM (1X10PK) STER	168212	1226681	4E05398	00768455122790
KALTOSTAT DRS 10X20CM (1X10) STER	168214	1052788	4E06012	00768455122813

Note – The information above illustrates all products/lots affected

FIGURE 1

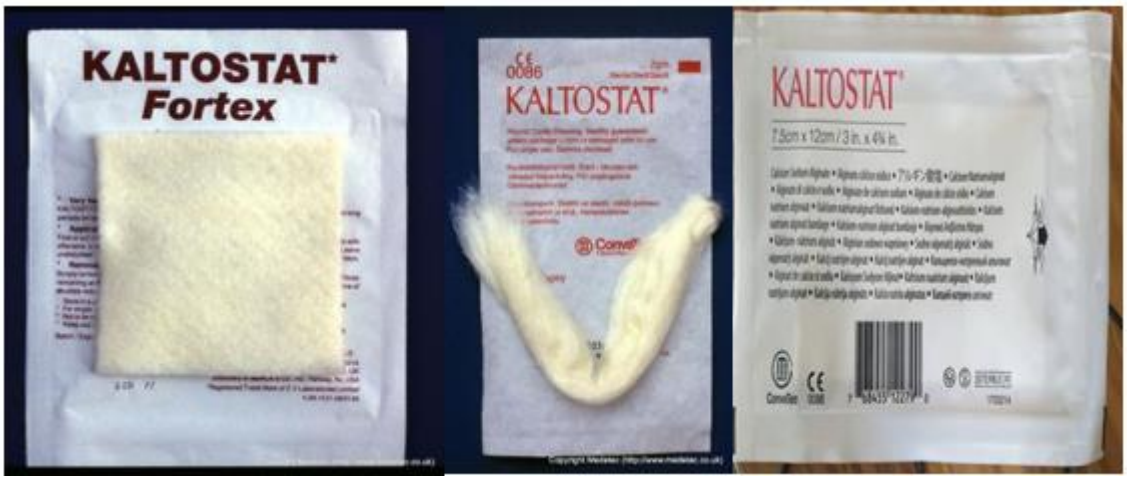

Figure 1 – Primary Packaging >> Guidance Image to support identification of affected product.

Our records indicate that you may have received the affected units. The affected units were distributed to the affected markets between **25th June 2024 to 12th July 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 action should be carried out at the distributor, wholesaler, retailer, and end-user level. Your assistance is required to prevent further distribution and inconvenience to customers. Please follow the ***"Your Responsibilities"*** section.

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.

The National Competent (Regulatory) Authority has been informed of this field safety notice.

At your disposal for further questions. Please contact Convatec Recall Department via email: fsca-id@convatec.com.

Convatec' s primary objectives are patient safety and providing customers with quality products. **We apologise for any inconvenience caused by this action** and, thank you in advance for your assistance on resolving this matter as quickly and effectively as possible.

Sincerely,

Head of IC/AWC – Regulatory Affairs

Steeve Lamvohee

Signed by:

Signer Name: Steeve Lamvohee
Signing Reason: I approve this document
Signing Time: Jul 18, 2024 | 7:50:37 PM BST
79126EF62CD04B7AA0479B4D5AA7AE98

Sincerely,

Authorised Representative

Rikke Eiland

Signed by:
Rikke Eiland

Signer Name: Rikke Eiland
Signing Reason: Jeg godkender dette dokument
Signing Time: jul 18, 2024 | 7:14:57 PM BST
822B10BC3BDE4D52B127413185588066

YOUR RESPONSIBILITIES

DISTRIBUTORS

1. Review this notification and ensure that all relevant personnel are aware of this FSN 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 FSN 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 unclear how to proceed, please contact Convatec Customer Services of your country.

Country	Email	Telephone
Austria	de.kundenservice@convatec.com	0800 162 4381
Belgium	nl.klantenservice@convatec.com	+32 2 352 89 56
Croatia	CISG.CUSTOMERSERVICE@convatec.com	N/A
France	fr.serviceclient@convatec.com	0800 358 480/ 01 56 47 18 00
Germany	de.kundenservice@convatec.com	0800 162 4381
Guadeloupe	fr.serviceclient@convatec.com	0800 358 480/ 01 56 47 18 00
Ireland	uk.customerservice@convatec.com	01244 284882
Malta	CISG.CUSTOMERSERVICE@convatec.com	+47 22-686095
Netherlands	nl.klantenservice@convatec.com	+31 348 436 987
Norway	customerservicenordic@convatec.com	N/A
Switzerland	de.kundenservice@convatec.com	0800 162 4381

WHOLESALES & RETAILERS

1. Review this notification and ensure that all relevant personnel are aware of this FSN communication.
2. Immediately locate and quarantine affected product in your inventory.
3. Liaise with your provider of the product to determine the next steps and/or compensation.
4. If you are in receipt of this communication and are still unclear how to proceed, please contact Convatec Customer Services of your country as per the table above.

END-USER/CONSUMER LEVEL

1. Review this notification and ensure that all relevant personnel are aware of this FSN communication.
2. Immediately locate and quarantine affected product in your inventory.
3. Liaise with your provider of the product to determine the next steps and/or compensation.
4. If you are in receipt of this communication and are still unclear how to proceed, please contact Convatec Customer Services of your country as per the table above.

APPENDIX 1

RESPONSE FORM

Immediately complete the response form.

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

Please return the completed form via the instructions below.

Issue Date: Jul-2024 Convatec FSCA Ref: TW-1943643

Original 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:	

☐	I confirm receipt, and acknowledgement of this notification	
☐	I have checked my inventory and I have product on hand	QTY
☐	I have checked my inventory, quarantined, and disposed of affected inventory	
☐	I have attached a Certificate of Destruction (COD) as requested evidence	
☐	I have identified customers that received or may have received affected product	
☐	I have informed the identified customers of this notification	Date Sent

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

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FSN ACKNOWLEDGEMENT

NAME	
POSITION	
SIGNATURE	
DATE (DD/MMM/YYYY)	

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.

A signed response form (Appendix 1) and COD if applicable, can be returned to your local Convatec Customer Services Representative or, to the Convatec Recall Department via fsca-id@convatec.com