Convatec Reference: TW-1939942

Notice Type: Original/New

Date: August-2024

Medical Device Recall Notification
TG Eakin Ltd

Dear Customer,

On behalf of the legal manufacturer, TG Eakin Ltd, Convatec Ltd is formally cascading a recall notification regarding Cohesive Small Seals / Product Code: 839002 to customers identified as affected. Therefore, you are receiving this communication as our records indicate that the affected units were distributed between 03-Apr-24 to 10-Jul-24.

This communication includes the original TG Eakin Ltd recall notice. Please review this information under Appendix 1 to understand the action in detail. Also included, is the “your responsibilities” section and Appendix 2 which will require your immediate attention and collaboration.

The Food and Drug Administration (FDA) and Health Canada have been informed accordingly of the recall action.

Convatec’ s primary objective is patient safety and providing customers with quality products. **On behalf of TG Eakin Ltd, we apologise for any inconvenience caused by this action.**

Thank you for your cooperation and Convatec remains at your disposal for further questions.

Sincerely,

Signed by:
Jared Ragone
Signer Name: Jared Ragone
Signing Reason: I approve this document
Signing Time: Aug 12, 2024 | 2:20:11 PM BST
2956DCE5D9484FA39ABFBDDCA5F7CB60

Jared Ragone

Senior Director, Quality

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Medical Device Recall

1. Description of the device

Model number

839002

Device description

Eakin Cohesive® small seals

Device configuration

Eakin Cohesive small seals are supplied in cartons of 20 devices. Each device within the carton is packed in a clear plastic blister which is sealed with a paper lid. The paper lid is printed with the device model number and description, as shown in section 3 below.

Device Lot number

109357C553

Device intended use

Eakin Cohesive small seals are intended to be used to protect the peristomal skin of a patient with a stoma from the denuding effects of stomal output.

Device intended users / indications for use

Eakin Cohesive small seals are intended to be used by patients with a stoma when they wish to protect the skin around their stoma from contact with stomal output.

2. Description of the issue

It has been identified that a number of cartons of 839002 Eakin Cohesive small seals with the Lot number 109357C553 (distributed exclusively in USA by Convatec Inc. and exclusively in Canada by Convatec Canada Ltd.) contain individually blistered Eakin Cohesive small seals which have been mis-labelled as 839005 Eakin Cohesive Slims seals. In some cases, all 20 individually blistered seals inside the carton may be labelled as 839005. In other cases, some cartons may contain a mixture of individually blistered seals labelled as 839002 or 839005. Most cartons will contain individually blistered seals which are correctly labelled as 839002. Any mis-labelled individually blistered seals will not be evident until the carton has been opened.

In all cases, the carton labelling is correct. All cartons with the Lot number 109357C553 are confirmed as containing the correct product - 839002 Eakin Cohesive small seals.

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3. Product images

839002 Carton front

839002 Carton rear – LOT number location highlighted.

839002 seal lid – **Correct label**

839005 seal lid – **Incorrect label**

4. Reason for this notification

This notification is provided to inform consignees that the individually blistered 839002 Eakin Cohesive small seals in a carton marked with Lot number 109357C553, may be wrongly labelled as 839005 Eakin Cohesive slims seals. The product within the individually blistered seal is correct, 839002 Eakin Cohesive small seal, and therefore **the product can be safely used as intended.** All individually blistered seals will perform as intended when used in accordance with the supplied instructions for use.

There is no risk to the end user arising from this issue which would result in an adverse event. However, TG Eakin Limited (legal manufacturer) supported by the distributors Convatec Inc. (USA) and Convatec Canada Ltd. have taken the decision to

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voluntarily remove the affected product from the market in order to minimise the potential of a negative user experience.

YOUR RESPONSIBILITIES

1. Review this notification and ensure that all relevant personnel are informed.
2. If you have distributed the affected product downstream, you are responsible for identifying these customers and issuing notification of the recall action.
3. Immediately locate and quarantine affected product in your inventory.
4. Complete **Appendix 2** and return to Convatec within 30 calendar days of receipt.
5. A review of the information you provide in accordance with **Appendix 2** will be completed.
6. In accordance with step 5 if the information is satisfactory, formal authorization from a Convatec Representative will be provided to proceed with product destruction.
7. 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 recall notice is included for traceability.
8. Immediately destroy all affected product and provide Convatec with a signed Certificate of Destruction (COD) as evidence to support reconciliation.
9. Your account will be credited for all destroyed product upon receipt of a signed form as per **Appendix 2** and a Certificate of Destruction (COD). **If you do not sufficiently produce Appendix 2 and a certificate of destruction a credit will not be issued.**
    a. Please ensure your account number is correctly identified on **Appendix 2.** If you do not know your account number, please liaise with customer services.
10. 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
USA	us.customerservice@convatec.com	800-582-6514
Canada	ca.customerservice@convatec.com	450-552-8083

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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: Aug-2024 Convatec Ref: TW-1939942

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 and I do not have product on hand	N/A
☐	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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Issue Date: Aug-2024 Convatec Ref: TW-1939942

Original Notice: X Revised Notice: N/A Revision Number: Rev.1

RECALL ACKNOWLEDGEMENT

NAME	
POSITION	
SIGNATURE	
DATE (DD/MMM/YYYY)	

A signed response form (Appendix 2) 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