Convatec Reference: TW-2830151
Issue Date: July 2026
Notice Type: New

Urgent: Field Safety Notice
Esteem Body™ Soft-Tap Convex Urostomy Pouch

Dear Customer,

Convatec is voluntarily initiating a Field Safety Corrective Action for selected batches of **Esteem Body™ Soft-Tap Convex Urostomy Pouches** due to the product not performing as intended which is resulting in leaks for a limited subset of products.

1. Description of the Issue

Through routine **complaint handling and post-market surveillance (PMS) activities**, Convatec identified an **increasing trend in complaints**, and as a result, an internal investigation was initiated.

This investigation determined the following:

- A **variability in the Soft-Tap interference fit** (i.e., the sealing interface between the plug and the tap/stem) in a limited subset of Esteem Body™ Soft-Tap Convex Urostomy Pouches.
- This variability may result in the product **not performing as intended**, specifically leading to **leakage from the Soft-Tap cap during use**.
- Reported instances have primarily occurred **following connection to a night drainage system**, where the integrity of the **plug-to-tap seal may be compromised**.

The issue is **isolated to specific Esteem Body™ Soft-Tap Convex Urostomy Pouches only**.

No other **Esteem Body™ products**, including urostomy batches not listed and, **Drainable or Closed-End pouch variants**, are impacted.

2. Affected Product Details

Details of the affected product codes and corresponding lot numbers are provided in **Appendix 2**.

Figure 1. Example affected product

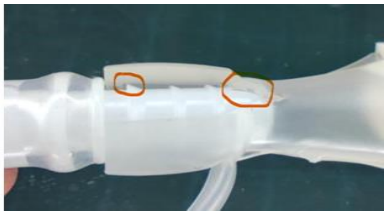

Figure 2. Example of Soft Tap seal area

How to identify

After disconnecting the soft tap from a night drainage system or leg bag, inspect the tap to ensure it continues to function correctly.

1. Check whether the tap remains securely sealed.
2. If no leakage is observed after disconnection, the seal can be considered effective and the pouch may continue to be used as intended.
3. Convatec does not advise avoiding disconnection to prevent leaks.

Important: This information is intended for patients who currently have an affected pouch in use while replacement product is obtained. Healthcare providers and distributors should continue to follow the actions described in this notice and should not distribute affected product.

Our records indicate that you may have received the affected units **distributed between 19-Sep-2025, to 12-May-2026.**

3. Patient Safety

The issue may result in leakage from the Soft Tap cap during use, which may lead to skin irritation, interruption of therapy, product replacement requirements, inconvenience, property damage, and other consequences associated with unintended leakage. Convatec is conducting this FSCA to remove affected product from the market and prevent further occurrence of the issue.

To date, Convatec has received 90 complaints associated with leakage of the affected product. Based on information currently available, no serious injuries have been reported in connection with these complaints.

4. Required Actions

4.1 Distributors, Wholesalers, Clinical Facilities, & Hospitals

Please take the following actions immediately:

- **Examine your inventory** and identify all affected product lots using the lot numbers provided in the enclosed Product Identification Table (**Appendix 2**).
- **Immediately quarantine and discontinue distribution, sale, transfer, and use** of all affected product to prevent further distribution or use.
- **Inform all appropriate personnel** within your organisation, including those responsible for inventory management, purchasing, distribution, and product use, of this FSCA.
- **If you have further distributed, transferred, or supplied any affected product, you must immediately notify all consignees and customers who may have received the affected product.** Provide them with a copy of this notification and instruct them to take the actions described in this notice.
    - **Important:** If not Convatec please contact the supplier from whom the product was purchased to report any affected inventory and obtain instructions regarding product disposition.
- **Acknowledgement:** Please confirm receipt of this notice and your compliance with the required actions by completing and returning the enclosed acknowledgement form (appendix 1) **to** european.customersupport@convatec.com no later than 07-Aug-2026.
- If affected product is identified within your inventory, Convatec will provide a **Certificate of Destruction (COD)** for completion.
- Following destruction, please **complete and return the signed Certificate of Destruction (COD)** to Convatec as evidence to support compliance with this action.

4.2 End-Users / Patients

Please take the following actions immediately:

Important: If not Convatec, please contact the supplier from whom the product was sourced/purchased to report any affected inventory and obtain instructions regarding product disposition.

- **Review your supplies:** Examine your personal supplies and determine whether you have any affected product identified in the Product Identification Table (**Appendix 2**).
- **Discontinue use and obtain replacement product:** If you identify affected product, discontinue use of the affected device and contact your supplier, healthcare provider, or Convatec representative to obtain replacement product as soon as possible.

- **Interim Instructions (if replacement product is not yet available):** If replacement product is not immediately available and continued use is necessary, follow the interim precautionary instructions provided in **Section 2** of this notice for performing leakage checks. These interim measures are temporary and do not replace the need to obtain replacement product as soon as possible.
- **Acknowledgement:** Please confirm receipt of this notice and your compliance with the required actions by completing and returning the enclosed acknowledgement form (appendix 1) **to** european.customersupport@convatec.com no later than 07-Aug-2026.
- Our customer care teams are available to assist you with any questions you may have regarding this communication and provide product alternatives if needed. Please contact

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4.3 Sales Representatives

- **Cease Distribution**
  - Immediately stop all sales, distribution, and promotion of affected products.
  - Do not supply affected stock to customers under any circumstances.
- **Identify and Segregate Inventory**
  - Review all personal stock, consignment stock, demonstration kits, and customer-held inventory (where visibility is available).
  - Identify affected lot numbers.
  - Dispose of the affected product
- **Notify Customers**
  - Promptly inform all affected end-users within your territory using the approved FSN
  - Ensure **only approved, final FSN wording is used** (no modification).
- **Regulatory Compliance**
  - Complete the Response Form below **(Appendix 1)** and return to european.customersupport@convatec.com within 15 days.
  - Complete a certificate of destruction (COD) (provided in the email package) and return within 15 days.

5. Transmission of Notice & Reporting

- This notice must be shared with all individuals within your organisation who need to be informed, as well as any external organisations to whom the potentially affected devices may have been supplied or transferred.
- Please ensure continued awareness of this notice and the associated actions for an appropriate period, so that the corrective measures remain effective across your organisation.
- All device-related incidents or complaints should be reported to the manufacturer, distributor, or local representative. Such reporting provides essential feedback for ongoing safety monitoring.
- Please continue to inform Convatec of any adverse events associated with this product through your usual reporting channels.

Reporting to Authorities
The regulatory authority in your country has been informed of this communication as required.

6. Contact information

Replacement product and general questions:

Country	Email	Telephone
Croatia	Export.CustomerSupport@convatec.com	N/A
Germany	de.kundenservice@convatec.com	0800 162 4381
Ireland	Export.CustomerSupport@convatec.com	N/A
Luxembourg	Be.klantenservice@convatec.com	02 352 89 56
Netherlands	Nl.klantenservice@convatec.com	+31 348 436 987
Norway	customerservicenordic@convatec.com	22-686095
Slovakia	European.CustomerSupport@convatec.com	N/A
Sweden	customerservicenordic@convatec.com	042-332010
Switzerland	de.kundenservice@convatec.com	0800 162 4381
United Kingdom	Uk.customerservice@convatec.com	01244 284882

Credits & acknowledgement form questions: european.customersupport@convatec.com
FSCA related questions: fsca-id@convatec.com

Convatec remains committed to transparency, regulatory compliance, and delivering high quality products
Thank you for your understanding and we apologise for any inconvenience this action may cause.

Sincerely,
Steeve Lamvohee

Signed by:
Steeve Lamvohee
Signer Name: Steeve Lamvohee
Signing Reason: I approve this document
Signing Time: Jul 14, 2026 | 10:39:20 PM BST
79126EF62CD04B7AA0479B4D5AA7AE98

Head of Regulatory Affairs

APPENDIX 1

RESPONSE FORM

- *Immediately complete*
- *If you have no affected product a completed response form is still required*
- *Please return the completed form via email* european.customersupport@convatec.com

Issue Date: July 2026 **CVT FSCA Ref:** TW-2830151

Original Notice: X **Revised Notice:** N/A **Revision Number:** 1

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

Account No:	
Business Name:	
Address:	

Yes	No		
		I confirm receipt, understanding and acknowledgement of this notification	
		I have checked my inventory, and I have **no product on hand**	
		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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ACTION ACKNOWLEDGEMENT

NAME	
POSITION	
SIGNATURE	
DATE	

APPENDIX 2

Country	Product SAP Code	Product ICC Code	Lot Number	Date of Manufacture	Basic UDI-ID
Croatia	1737645 1737649	423704 423705	6A00217 6A01522	02/01/2026 07/01/2026	768455OST0003EZ