

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This notice is to inform you of a product recall involving **Convatec Esteem Body Soft-Tap Convex Urostomy Pouch** due to the product not performing as intended which is resulting in leaks for a limited subset of products.

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.

Questions: Contact cic@convatec.com **or 1-800-422-8811.**

<u>Product SAP Code</u>	<u>Product ICC Code</u>	<u>Lot Number</u>	<u>Date of Manufacture</u>	<u>Basic UDI-ID</u>
1737645	423704	5H04775	28/08/2025	768455OST0003EZ
1737649	423705	5J00257	02/09/2025	
1737671	423712	5J00475	03/09/2025	
1737672	423713	5J00903	05/09/2025	
1737673	423714	5J01426	08/09/2025	
1737674	423715	5J01512	11/09/2025	
1737675	423716	5J02234	12/09/2025	
1737676	423717	5J02340	01/10/2025	

1737677	423718	5J02361	02/10/2025
1737681	423722	5J02362	03/10/2025
1737682	423723	5J02732	06/10/2025
1737684	423725	5K00013	07/10/2025
1737685	423726	5K00338	09/10/2025
1737686	423727	5K00713	13/10/2025
		5K01320	31/10/2025
		5K01321	03/11/2025
		5K01500	04/11/2025
		5K01541	06/11/2025
		5K02079	10/11/2025
		5K02080	12/11/2025
		5K02095	13/11/2025
		5K02104	25/11/2025
		5K03003	02/01/2026
		5K03008	07/01/2026
		5K06686	08/01/2026
		5L00231	09/01/2026
		5L00444	
		5L01041	
		5L01042	
		5L01162	
		5L01935	
		5L02306	
		5L02524	

5L04677

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6A01521

6A01717

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