

URGENT MEDICAL DEVICE RECALL

*Recd 10/28/26
JS*

October 9, 2026

Dear Valued McKesson Customer:

Convatec has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Recall regarding specific lot(s) of their ESENTA Stomahesive Paste. This notice has been issued due to a quality related issue involving the potential presence of foreign matter within the product. Affected product first shipped December 17, 2025.

McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For questions regarding this notification, please contact Convatec at **(800) 422-8811**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table below for a list of affected item(s) and lot number(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)	Exp. Date
116253	183910	PASTE, SKIN BARRIER STOMAHESIVE TU 2OZ	5J04201	09/01/2030
			5K00858	10/01/2030
			5L00433	11/01/2030
			5L02930	11/01/2030
			6A03082	01/01/2031
			6B00827	02/01/2031
			6E01386	05/01/2031
			6E03598	05/01/2031

McKesson Customer Instructions:

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed above. If you have no product matching the affected item(s) and lot number(s), no further action is needed.
- 2.) A copy of the Urgent Medical Device Recall from Convatec has been included for reference.
- 3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, **please respond within 30 days**. **Please note:** Credit will only be issued for the affected Lot(s) of the product(s) listed above and entered on the reply form. **Please place a new order for replacement product if there is an immediate need.**
- 4.) Please dispose of any affected product in your possession in accordance with your institution's policies and procedures.
- 5.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this notification.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc.
Medical Device Recall Reply Form: RC-2026-255
Convatec - ESENTA Stomahesive Paste

October 9, 2026

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at (866) 871-0270 should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account: 20037573 District: 22610000
CARELINC MEDICAL EQUIP & SUPP
ATTN: RISK MANAGEMENT
89 54TH ST SW STE 1
GRAND RAPIDS, MI 49548-5503

☐ I acknowledge that I DO HAVE product affected by this notification and have disposed of this product in accordance with my institution's policies and procedures.

Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			116253	183910	PASTE, SKIN BARRIER STOMAHESIVE TU 2OZ

*Discard Affected lot numbers only

*** The affected lot number(s) are listed on the McKesson customer letter. Please dispose of affected product in accordance with your institution's policies and procedures.**

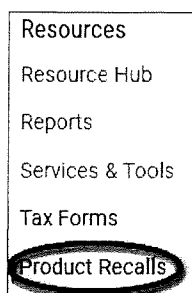
Credit will only be issued for product(s) listed above with affected lots.

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

See instructions on the reverse side of this form to access McKesson Medical-Surgical's online product ordering system, "SupplyManager", for a fillable form.

**Instructions for the McKesson Medical-Surgical online product ordering system – “SupplyManager”,
to access and download a “fillable” PDF reply form.**

- 1) It is important to download the correct reply form for the specific recall you are responding to.
 - a. Reply forms have a specific designation, example: RC-202X-XXX.
 - “202X” is the recall year, and “XXX” is the 3-digit unique numeric identifier for the recall.
- 2) Go to <https://mms.mckesson.com/> and log in to “SupplyManager”, with your username and password.
- 3) On the home page, under ‘Essential Tasks’ click ‘Your Account.’ Under ‘Resources’ a support link titled “Product Recalls” can be found on the right side.
- 4) Click on the hyperlink “Product Recalls” (this will open a listing of recalls for the last 3 months).



- 5) On the recalls list page, locate the “Find” box.
 - a. From the drop-down options, select one of the following: “Keyword”, “McKesson Item #” or “Manufacturer”.
 - b. Enter a Keyword, McKesson Item #, or Manufacturer name in the Find box and click “Find”.

Find Manufacturer ▼

- c. A list of issued recalls will be made visible for you to select from.

- 6) Click on the blue hyperlink, found under the heading “Recall Notice,” for the notice details you want to access.

Manufacturer	Recall Notice	Issued ▼
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- 7) The PDF customer documents associated with the notice will be displayed, *this includes the reply form to download and complete for your response.*
- 8) Click on the hyperlink(s) to open the Customer Document(s). Save/Download this document to your computer. Once the documents are saved, close out the document window.
- 9) Submit completed reply form to MMSRecalls@McKesson.com.
- 10) If you wish to view additional recalls, return to the home recall page by clicking the blue “View All Recalls” button at the upper right corner of the page above the blue alert banner.

URGENT MEDICAL DEVICE RECALL

ESENTA™ Stomahesive Paste

Issue Date: Oct-2026
Reference: TW-3258356
Subject: Voluntary Field Action for Specific Lots

Dear Customer,

Convatec is conducting a voluntary field action (removal) of specific lots of **ESENTA™ Stomahesive Paste** due to a quality related issue involving the potential presence of foreign matter within the product. According to our records, your organization may have received affected lots of ESENTA™ Stomahesive Paste. Immediate action is required to identify, quarantine, and discontinue further distribution or use of affected product.

Affected Product (*Globally*)

Product Code	Affected LOTs	Product Description	Primary UDI
1729233	6C03499	ESENTA SHESIVE PASTE(1X60GTUBE)	00768455169900
1729236	5K03776 5L00431 5L00432 5L02607 5M02351 5M03521 6A04022 6E01525 6E05356 6E05929	ESENTA SHESIVE PASTE(1X56.7GTUBE)	00768455169931
1739996	5J04201 5K00858 5L00433 5L02930 6A03082 6B00827 6E01386 6E03598	ESENTA S/HESIVE PASTE 1TUBEX56.7G	00768455209255
1739997	6C03991	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209262
1739998	6B00828 6C05168 6D02979	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209279
1739999	6A03083 6B00830 6D00838 6E01524	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209286
1740000	6A04010	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209293
1740002	6C03980 6D00839 6E03597	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209316
1740003	6E01523	ESENTA S/HESIVE PASTE 1TUBEX60G	00768455209323

Country specific affected product identification details provided in **Appendix 2** and product label provided in **Appendix 3**.

The affected lots of **ESENTA™ Stomahesive Paste** were distributed between **17-Dec-25 to 08-Sep-26** in the **USA**.

Reason

Through routine complaint handling and quality monitoring activities, a product quality issue was identified involving the presence of foreign matter in certain units of **ESENTA™ Stomahesive Paste**.

Subsequent investigation determined that existing controls at a third-party manufacturing facility were not fully effective in preventing contamination of Convatec materials. As a result, there is the potential for foreign contamination of affected product lots listed within the scope of this notification.

Based on the investigation findings and as a precautionary measure to protect product quality and patient safety, Convatec is voluntarily recalling the affected lots of **ESENTA™ Stomahesive Paste**.

Potential Risk

The presence of foreign matter in the affected product may impact product quality and intended performance. Potential adverse effects associated with the use of affected product may include local inflammatory response, minor infection, skin irritation, rash, mucosal irritation, or allergic reaction.

The quality defect may be detected through visual inspection prior to application or use.

To date, no adverse events related to this issue have been reported to Convatec. One (1) customer complaint involving foreign matter was received and led to the investigation and subsequent corrective action.

Action Required

Distributors & Healthcare Facilities

Take the following actions without undue delay;

- **Examine your inventory** and identify all affected product lots using the details 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 organization, including those responsible for inventory management, purchasing, distribution, and product use, of this recall action.
- **If you have distributed any affected product further**, immediately identify all customers who received the affected lots and notify them of this corrective action. A copy of this communication can be provided accompanied with a cover letter from your organization. Maintain records of all customer notifications and provide confirmation of completion upon request.
- ~~**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 us.customerservice@convatec.com within 30 days~~
- ~~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.~~

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



Healthcare Professionals

At this time, Convatec has not received reports indicating that patient intervention is required solely as a result of the issue described in this notification. Healthcare professionals should continue to use their clinical judgment when evaluating patients who may have been exposed to the affected device.

- Identify, quarantine, and dispose of all affected product.
- Discontinue use of affected product.
- Inform relevant staff members of this action.
- Report any adverse events or complaints associated with the affected device to Convatec and applicable regulatory authorities, as required.

End Users / Patients

If you possess any affected **ESENTA™ Stomahesive Paste** identified in this notice (**Appendix 2**):

- Stop using the product immediately.
- Set the product aside and do not use it.
- Contact your healthcare provider, supplier, pharmacy, or Convatec representative (me+ Team) for further instructions.
- Retain the product and lot number information until you receive further guidance.

If you have used affected product and experience any unexpected symptoms, including irritation, rash, inflammation, signs of infection, or other concerning symptoms, contact your healthcare professional promptly.

Convatec Sales Representatives

Please take the following actions immediately:

- Familiarize yourself with this recall notification and the affected lot numbers.
- Immediately stop distribution, and promotion of affected products.
- Review all personal stock, consignment stock, and demonstration kits.
- Complete the Response Form below (**Appendix 1**) and return to us.customerservice@convatec.com within 30-days.
- Complete a certificate of destruction (COD) (provided in the email package) and return.
- Support customers in identifying affected product within inventory, where requested.
- Escalate all reports of complaints, quality concerns, potential adverse events, or customer questions through established Convatec processes.

Corrective Action Being Taken by Convatec

Convatec has initiated this voluntary field action to remove affected product from the market to prevent potential safety concerns and product performance issues.

Appropriate corrective actions will be implemented to address and mitigate this issue, and to strengthen process controls, ensuring ongoing compliance with product quality and regulatory requirements.

We are working closely with our partner and customers to manage the situation effectively and to support customers in maintaining continuity of care and minimising potential disruption to patient treatment.

Transmission of Notice & Reporting

- This notice must be shared with all individuals within your organization who need to be informed, as well as any external organizations 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 organization.
- 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.
- This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).
- Adverse reactions or quality problems experienced with the use of this product can be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. –
 - Complete and submit the report Online: www.fda.gov/medwatch/report.htm
 - Regular Mail or Fax: Download form <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178
- Please continue to inform Convatec of any adverse events associated with this product through your usual reporting channels.

Contact information

Customer Services: cic@convatec.com or 1-800-422-8811

Response Form & Credits: us.customerservice@convatec.com

Field Action Questions: fsca-id@convatec.com

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

Sincerely,
Tara Turney

Signed by:

 Signer Name: Tara Turney
Signing Reason: I approve this document
Signing Time: Oct 7, 2026 | 10:46:54 PM BST
51FC49C4BB42442A94A091E31D53F71B
Senior Director
Regulatory Affairs

APPENDIX 3 – Packaging Identification

