

**URGENT MEDICAL DEVICE RECALL**

August 11, 2025

Dear Valued McKesson Customer:

Integra LifeSciences has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Recall regarding all unexpired lots of their MediHoney Wound & Burn products. This notice has been issued because packaging failures were identified which could lead to a breach in the sterile barrier. The specific potential failures are one or several of the following, tube foil induction seal is not completely sealed to the tube, inadequate sealing of sterile barrier packaging, shipping boxes do not adequately protect device during transportation and tube twist-off cap failure. Affected product first shipped July 14, 2021.

This Urgent Medical Device Recall is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For clinical inquiries, please contact Integra LifeSciences at **(800) 654-2873**.

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 for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)
825485	31505	DRESSING, OINT MEDIHONEY TWISTOFF STR .5OZ TU (10	All unexpired lots
699433	31515	DRESSING, MEDI-HONEY 1.5OZ (12TU/CS)	
710610	31535	DRESSING, MEDIHONEY 3.5OZ TU (12/CS)	
981162	31612	DRESSING, MEDIHONEY HCS N/ADH 8X12 (2/BX 5BX/CS)	
1030998	31620	DRESSING, MEDIHONEY NON-ADH HYDROGEL 2.4"X2.4" (10/BX 5BX/CS)	
821087	31622	DRESSING, WND MEDIHONEY HYDROGEL 2.4X2.4 (10/BX5BX)	
1030999	31640	DRESSING, MEDIHONEY NON-ADH HYDROGEL 4.3"X4.3"(10/BX 5BX/CS)	
823279	31644	DRESSING, WOUND MEDIHONEY 4.3X4.3 (10/BX 5BX/CS)	
1031000	31720	DRESSING, MEDIHONEY NON-ADH HYDROGEL 2.8"X2.8"(10/BX 5BX/CS)	
821103	31722	DRESSING, WND MEDIHONEY HYDROGL 3.5X3.5 2.8PAD(10/	
1031001	31740	DRESSING, MEDIHONEY NON-ADH HYDROGEL 4.5"X4.5" (10/BX 5BX/CS)	
860465	31744	DRESSING, MEDIHONEY HCS ADH 4.5X4.5 (10/BX 5BX/CS) DERSCI	

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**McKesson Customer Instructions:**

- 1.) Immediately discontinue use of any product matching the affected items and lot numbers listed in the item table. If you have no products matching the affected items and lot numbers, no further action is needed.
- 2.) A copy of the Urgent Medical Device Recall from Integra LifeSciences 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](mailto: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:** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.
  - **Please place a new order for replacement product if there is an immediate need.**
- 4.) If you have further distributed any of the items referenced in this notification, provide your accounts with a copy of this Urgent Medical Device Recall and request that they return the affected product directly to you.

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](mailto:MMSRecalls@McKesson.com) or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc.  
 Device Recall Reply Form: RC-2025-157  
 Integra LifeSciences MediHoney Wound & Burn Products

August 11, 2025

Complete this reply form and return all pages immediately via email to [MMSRecalls@McKesson.com](mailto: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: \_\_\_\_\_ Ship to Acct Number: \_\_\_\_\_

Your Name: \_\_\_\_\_ Email Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

Account Name: \_\_\_\_\_

Address: \_\_\_\_\_

City, State Zip: \_\_\_\_\_

I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Qty	Unit of Measure	MMS #	MFG Catalog #	Description
		825485	31505	DRESSING, OINT MEDIHONEY TWISTOFF STR .5OZ TU (10
		699433	31515	DRESSING, MEDI-HONEY 1.5OZ (12TU/CS)
		710610	31535	DRESSING, MEDIHONEY 3.5OZ TU (12/CS)
		981162	31612	DRESSING, MEDIHONEY HCS N/ADH 8X12 (2/BX 5BX/CS)
		1030998	31620	DRESSING, MEDIHONEY NON-ADH HYDROGEL 2.4"X2.4" (10/BX 5BX/CS
		821087	31622	DRESSING, WND MEDIHONEY HYDROGEL 2.4X2.4 (10/BX5BX
		1030999	31640	DRESSING, MEDIHONEY NON-ADH HYDROGEL 4.3"X4.3"(10/BX 5BX/CS)
		823279	31644	DRESSING, WOUND MEDIHONEY 4.3X4.3 (10/BX 5BX/CS)
		1031000	31720	DRESSING, MEDIHONEY NON-ADH HYDROGEL 2.8"X2.8"(10/BX 5BX/CS)
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		1031001	31740	DRESSING, MEDIHONEY NON-ADH HYDROGEL 4.5"X4.5" (10/BX 5BX/CS
		860465	31744	DRESSING, MEDIHONEY HCS ADH 4.5X4.5 (10/BX 5BX/CS)

\*Return Affected lot numbers only

**\* Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected lot numbers are listed on the McKesson customer letter.**

**If you are on a McKesson truck route, a delivery professional will pick up the affected products, otherwise you will receive UPS return label(s) via email or fax.**

I am on a McKesson truck route, please schedule a delivery professional pick up.

Please send my UPS/Return label by  Fax or  Email. Number of UPS Parcels to be returned: \_\_\_\_\_

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

# FIRST NOTIFICATION

## URGENT: VOLUNTARY MEDICAL DEVICE RECALL

### MediHoney® Wound & Burn Products

August 05, 2025

Dear Valued Integra Customer/Distributor:

**Purpose of this Letter** - Integra LifeSciences is voluntarily recalling the MediHoney® Wound & Burn products listed in **Table 1**.

**Reason for Voluntary Recall** - Packaging failures were identified related to the MediHoney Wound & Burn products, which could lead to a breach in the sterile barrier. The specific potential failures are one or several of the following, and are matched to each SKU in **Table 1**, under 'Issue #'. The issues include:

1. Tube foil induction seal is not completely sealed to the tube
2. Inadequate sealing of sterile barrier packaging
3. Shipping boxes do not adequately protect device during transportation
4. Tube twist-off cap failure

Across all affected MediHoney products, a total of 71 complaints have been received worldwide regarding the packaging failures as of May 13, 2025. Out of the 71 complaints, two (2) complaints were reported as serious injuries.

#### Risk To Health

1. Per the Health Hazard Evaluations (HHE), the potential harm is infection if a sterile barrier breached product is used on a patient. Additionally, the inability to use the device due to packaging failures may cause inconvenience to the user and delay care.
2. There is no long-range health consequences expected due to this issue.
3. If you have already used the products affected by this recall and standard operative care was followed, **there is no additional patient follow-up required**.

#### Actions to Take

<b>Customers (Medical Facility)</b>	<b>Distributors</b>
<ol style="list-style-type: none"> <li>1. Complete the 'Medical Facility Acknowledgement Form' provided.               <ol style="list-style-type: none"> <li>a. If you have units of the impacted product (Table 1) <b>remove them immediately from service and quarantine them.</b></li> <li>b. If you have affected product, check the box "I do have affected product." Record the lot number and total quantity of the affected product that you have.</li> <li>c. If you <b>DO NOT</b> have affected product, check the box, "I do not have affected product."</li> </ol> </li> <li>2. Forward this notice to those who utilize the product so they are aware of this recall and can identify any affected product that may remain in clinical areas.</li> <li>3. Complete the entirety of the Acknowledgement Form and send via email to <a href="mailto:FCA4@integralife.com">FCA4@integralife.com</a> or FAX to 1-609-750-4220.               <ol style="list-style-type: none"> <li>a. Keep a copy of the form for your records.</li> </ol> </li> </ol>	<ol style="list-style-type: none"> <li>1. Complete the 'Distributor Acknowledgement Form' provided.               <ol style="list-style-type: none"> <li>a. If you have products listed in <b>Table 1</b>, <b>remove the product from further distribution.</b></li> <li>b. If you have affected product, check the box "I do have affected product." Record the lot number and total quantity of affected product that you have.</li> <li>c. If you <b>DO NOT</b> have affected product, check the box, "I do not have affected product."</li> </ol> </li> <li>2. Complete the entirety of the Acknowledgement Form and send via email to <a href="mailto:FCA4@integralife.com">FCA4@integralife.com</a> or FAX to 1-609-750-4220.               <ol style="list-style-type: none"> <li>a. Keep a copy of the form for your records.</li> </ol> </li> <li>3. Check your customer traceability records and notify them if they have any shipments of above catalog and lot numbers.</li> <li>4. Modify the acknowledgement form to create one from you to your customers.</li> <li>5. Collect completed response forms and affected product from your customers and indicate total quantities and lots in distributor reply form (Appendix 2).</li> </ol>
<p>REGARDLESS OF WHETHER YOU HAVE AFFECTED PRODUCT TO RETURN,  <b>A COMPLETED ACKNOWLEDGEMENT IS REQUIRED</b></p>	

**Impacted Product Information** - Our records indicate that you may have received one or more of the products listed in **Table 1**.

**FIRST NOTIFICATION**  
**URGENT: VOLUNTARY MEDICAL DEVICE RECALL**  
**MediHoney® Wound & Burn Products**

**Table 1: Impacted Product Information**

Manufacturer Product # (Catalog #)	Issue #	Product Name (Description)	UDI Number	Lot # Expiration Date	Distribution Dates (MM/DD/YYYY)
31515	1,2,3	MEDIHONEY TUBE - 1.5 FL OZ (44 ML) – W/APPLICATOR- STERILE	10381780486824	All unexpired lots	09/20/2021 to 03/28/2025
31535	1,2,3	MEDIHONEY TUBE - 3.5 FL OZ W/APPLICATOR - STERILE	10381780486831	All unexpired lots	07/14/2021 to 02/12/2025
31505	2, 3, 4	MEDIHONEY IN TUBE .5 FL OZ, TWISTOFF - STERILE	10381780486930	All unexpired lots	02/22/2022 to 03/26/2025
31612	2	MEDIHONEY HCS 8"X12" BURN DRESSING STERILE 1'S, 2/BOX X 5...PK:10/CS	10381780486947	All unexpired lots	03/18/2024 to 03/19/2025
31620	2	MEDIHONEY HYDROGEL 2.4" X 2.4" STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471370	All unexpired lots	03/26/2024 to 03/25/2025
31622	2	MEDIHONEY HYDROGEL 2.4" X 2.4" SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471356	All unexpired lots	07/31/2023 to 07/30/2024
31640	2	MEDIHONEY HYDROGEL 4.3" X 4.3" STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471400	All unexpired lots	08/31/2023 to 03/24/2025
31644	2	MEDIHONEY HYDROGEL 4.3" X 4.3" SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471363	All unexpired lots	07/31/2023 to 07/01/2024
31720	2	MEDIHONEY HYDROGEL 2.8" X 2.8" ADHESIVE STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471417	All unexpired lots	04/03/2023 to 03/24/2025
31722	2	MEDIHONEY HYDROGEL 2.8" X 2.8" ADHESIVE SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471387	All unexpired lots	01/10/2024 to 01/27/2025
31738	2	MEDIHONEY HCS 3" X 8" STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780486961	All unexpired lots	02/06/2025 to 03/13/2025
31740	2	MEDIHONEY HYDROGEL 4.5"X 4.5" ADHESIVE STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471424	All unexpired lots	07/05/2024 to 03/21/2025
31744	2	MEDIHONEY HYDROGEL 4.5" X4.5" ADHESIVE SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS	10381780471394	All unexpired lots	12/15/2023 to 11/28/2024

- Integra's receipt of this form confirms achievement of a level of effectiveness in communicating this information.
- We recommend you maintain a copy of this notification and ~~signed copy of the acknowledgement form for your records.~~
- Regulatory agencies such as the FDA perform audits of field actions of this nature to verify that customers have been notified and understand the nature of the field action.

For questions regarding these instructions, please contact Customer Service:

Monday - Friday 8:00 AM – 8:00 PM EST  
 USA: 1-800-654-2873      email: [custsvcni@integralife.com](mailto:custsvcni@integralife.com)

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Integra is dedicated to patient safety and manufacturing excellence. We continue to make numerous quality improvements and investments in our facilities around the world. In addition, we are improving our processes in accordance with applicable regulations. We sincerely apologize for any inconvenience this voluntary recall may cause and thank you for your cooperation in this effort.

Sincerely,



Mary O'Neill,  
 Director, Post-Market Surveillance  
 Quality Assurance  
 Integra LifeSciences

**Appendix 1:** Field Safety Notice Customer Reply Form (1 page)  
**Appendix 2:** Field Safety Notice Distributor Reply Form (1 page)