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

September 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

Customers (Medical Facility)	Distributors
1. Complete the 'Medical Facility Acknowledgement Form' provided. a. If you have units of the impacted product (Table 1) **remove them immediately from service and quarantine them.** 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. c. If you **DO NOT** have affected product, check the box, "I do not have affected product." **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. **3.** Complete the entirety of the Acknowledgement Form and send via email to FCA4@integralife.com **or FAX to 1-609-750-4220.** a. Keep a copy of the form for your records.	**1.** Complete the 'Distributor Acknowledgement Form' provided. a. If you have products listed in **Table 1, remove the product from further distribution.** 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. c. If you **DO NOT** have affected product, check the box, "I do not have affected product." **2.** Complete the entirety of the Acknowledgement Form and send via email to FCA4@integralife.com **or FAX to 1-609-750-4220.** a. Keep a copy of the form for your records. **3.** Check your customer traceability records and notify them if they have any shipments of above catalog and lot numbers. **4.** Modify the acknowledgement form to create one from you to your customers. **5.** Collect completed response forms and affected product from your customers and indicate total quantities and lots in distributor reply form (Appendix 2).
REGARDLESS OF WHETHER YOU HAVE AFFECTED PRODUCT TO RETURN, **A COMPLETED ACKNOWLEDGEMENT IS REQUIRED**	

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

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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: custsvcnj@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)

SECOND NOTIFICATION
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Medical Facility Acknowledgement Form (FOR CUSTOMERS ONLY)

Response is required
Please complete and return promptly

Please fill out this form and return to:
FCA4@integralife.com or FAX to 1-609-750-4220

Customers *(Complete all sections & check all that apply)*:

1. ☐ I have received, read, and understand the information provided in the Voluntary Medical Device Recall Notice. I have/will comply with the Voluntary Medical Device Recall Notice.

2. Are there any adverse events associated with this issue?
   ☐ Yes ☐ No

If yes, please explain:

3. **Impacted Product**

   ☐ **I DO NOT have affected product or**
   ☐ **I have affected product**. Please complete the questions in the table below.

Manufacturer Product # (Catalog #)	Product Name (Description)	Quantity Unopened or full case(s)	Quantity Loose units from opened case(s)	Lot Number(s)
31515	MEDIHONEY® TUBE - 1.5 FL OZ (44 ML) – W/APPLICATOR- STERILE			
31535	MEDIHONEY® TUBE - 3.5 FL OZ W/APPLICATOR - STERILE			
31505	MEDIHONEY IN TUBE .5 FL OZ, TWISTOFF - STERILE			
31612	MEDIHONEY HCS 8"X12" BURN DRESSING STERILE 1'S, 2/BOX X 5...PK:10/CS			
31620	MEDIHONEY HYDROGEL 2.4" X 2.4" STERILE 1'S, 10/BOX X 5...PK:50/CS			
31622	MEDIHONEY HYDROGEL 2.4" X 2.4" SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS			
31640	MEDIHONEY HYDROGEL 4.3" X 4.3" STERILE 1'S, 10/BOX X 5...PK:50/CS			
31644	MEDIHONEY HYDROGEL 4.3" X 4.3" SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS			
31720	MEDIHONEY HYDROGEL 2.8" X 2.8" ADHESIVE STERILE 1'S, 10/BOX X 5...PK:50/CS			
31722	MEDIHONEY HYDROGEL 2.8" X 2.8" ADHESIVE SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS			
31738	MEDIHONEY HCS 3" X 8" STERILE 1'S, 10/BOX X 5...PK:50/CS			
31740	MEDIHONEY HYDROGEL 4.5"X 4.5" ADHESIVE STERILE 1'S, 10/BOX X 5...PK:50/CS			
31744	MEDIHONEY HYDROGEL 4.5" X4.5" ADHESIVE SHEET STERILE 1'S, 10/BOX X 5...PK:50/CS			

4. **Respondent Information**

Company / Hospital / Medical Facility:			
Street Address:		City, State, Zip Code:	
Telephone:		Email:	
Name (individual completing form):		Title:	
Name / Signature:		Date:	