MCKESSON

URGENT MEDICAL DEVICE RECALL

February 17, 2026

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 during an investigation, packaging failures were identified which could lead to a breach in the sterile barrier. Affected product first shipped August 5, 2020.

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)
788894	31815	DRESSING, MEDIHONEY GEL STR 1.5OZ (12/CS)	All unexpired lots
788895	31805	DRESSING, MEDIHONEY GEL STR TU0.5OZ (10/BX 4BX/CS)	All unexpired lots
688573	31012	DRESSING, MEDI-HONEY 3/4"X12" (5/BX 4BX/CS)	All unexpired lots
683998	31022	DRESSING, MEDI-HONEY 2"X2" (10/BX 10BX/CS)	All unexpired lots
702990	31045	DRESSING, MEDI-HONEY 4"X5" (10/BX 5BX/CS)	All unexpired lots

McKesson Customer Instructions:

1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in the item table. If you have no products matching the affected item(s) and lot number(s), 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 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 item(s) referenced in this notification, provide your accounts with a copy of this Urgent Medical Device Correction 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 or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc. February 17, 2026
Device Recall Reply Form: RC-2026-023
Integra LifeSciences MediHoney Wound & Burn Dressings and Gel

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: _____ 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
		788894	31815	DRESSING, MEDIHONEY GEL STR 1.5OZ (12/CS)
		788895	31805	DRESSING, MEDIHONEY GEL STR TU0.5OZ (10/BX 4BX/CS)
		688573	31012	DRESSING, MEDI-HONEY 3/4"X12" (5/BX 4BX/CS)
		683998	31022	DRESSING, MEDI-HONEY 2"X2" (10/BX 10BX/CS)
		702990	31045	DRESSING, MEDI-HONEY 4"X5" (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 or call (800) 688-8840.

URGENT: VOLUNTARY MEDICAL DEVICE RECALL

MediHoney® Wound & Burn Dressings and Gel

January 16th, 2026

Dear Valued Integra Customer/Distributor:

Reason for Communication:

This letter is to notify you that Integra LifeSciences is voluntarily recalling (removing) the MediHoney® Wound & Burn products listed in **Table 1.**

- During an investigation, packaging failures were identified related to the MediHoney® Wound & Burn products, which could lead to a breach in the sterile barrier.
- Across all affected MediHoney products, 17 complaints have been received worldwide from 01-Jan-2020 to 25-Sep-2025. Out of the 17 complaints, eleven (11) complaints were reported as serious injuries including infections and skin reactions.

Table 1: Impacted Product Information

Product Name	SKU	UDI #	Affected Lots*
MEDIHONEY® CALCIUM ALGINATE DRESS ROPE, ¾" X 12"	31012	10381780486909	All unexpired lots
MEDIHONEY® CALCIUM ALGINATE DRESSING, 2" X 2"	31022	10381780486916	All unexpired lots
MEDIHONEY® CALCIUM ALGINATE DRESSING, 4" X 5"	31045	10381780486923	All unexpired lots
MEDIHONEY® GEL IN TUBE, .5 FL OZ TWISTOFF – STERILE	31805	10381780486978	All unexpired lots
MEDIHONEY® GEL IN TUBE, 1.5 FL OZ FLIPCAP – STERILE	31815	10381780486886	All unexpired lots

*All MediHoney® Wound & Burn Products are now to be recalled at the date of this communication.

With this communication, all MediHoney® products are now recalled. **If you have expired products, please ensure that you discard them per your facility's policies and procedures and that you do not use them.**

Risk to Health - Per the Health Hazard Evaluation conducted for this issue:

- Per the Health Hazard Evaluations (HHE), the potential harm is infection, possible serious 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 delays and/or complications in wound care and healing.
- If you have already used the products affected by this recall, there is no additional patient follow-up required unless there are signs of infection. However, if currently in use please discontinue use immediately and follow up with your primary care physician for signs of infection.

Actions to Take:

Patient/End User
1. Immediately discontinue use of the product affected by this recall ~~and return any unused product~~. **2.** If you have used the product and have signs of wound infection follow-up with your medical provider. **3.** If you experience an injury or adverse event please report it to the manufacturer and to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax. Online: www.fda.gov/medwatch/report.htm

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~~. **4.** ~~When your form is received, and it is noted that you have affected product, Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product. For returned product, you may request credit~~.	**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 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)~~. **6.** ~~When your form is received, and it is noted that you have affected product, Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product. For returned product, you may request credit~~. **~~DO NOT SEND THE DISTRIBUTOR FORM TO YOUR CUSTOMERS.~~ IF YOUR CUSTOMERS CONTACT US, WE WILL NOT BE ABLE TO DIRECTLY ASSIST THEM. WE WILL DIRECT THEM BACK TO YOU.**

~~REGARDLESS OF WHETHER YOU HAVE AFFECTED PRODUCT TO RETURN,~~

~~**A COMPLETED ACKNOWLEDGEMENT IS REQUIRED**~~

~~Receipt of this form confirms that Integra has achieved a level of effectiveness in communicating this information~~. We recommend you also 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.

Should you have any questions regarding these instructions, please contact your Integra Sales Representative or Customer Service:

Monday to Friday 8:00 a.m. – 8:00 p.m. EST

1-800-654-2873 or custsvcnj@integralife.com.

In addition, 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:

Online: www.fda.gov/medwatch/report.htm
Mail: Medwatch, Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852
Fax: 800-332-0178 (toll-free)

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 (2 pages)~~

~~**Appendix 2:** Field Safety Notice Distributor Reply Form (2 pages)~~