MCKESSON

URGENT MEDICAL DEVICE CORRECTION

September 23, 2024

Dear Valued McKesson Customer:

Integra LifeSciences has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Correction regarding all lots within expiry of their MediHoney Wound & Burn Dressing Paste. This notice has been issued due to the potential for pinholes in the applicator pouch film which creates a sterility concern. The paste is not impacted by this sterility concern. There is no risk to the end user if the applicator is not used to apply the paste directly on the wound. Affected product first shipped December 17, 2020.

This Urgent Medical Device Correction 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 Customer Service 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 below for a list of affected item(s) previously distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)	Exp. Date
710610	31535	DRESSING, MEDIHONEY 3.5OZ TU (12/CS)	All Lots distributed from 12/17/2020 to 07/22/2024	08/01/2024 to 06/01/2028
699433	31515	DRESSING, MEDI-HONEY 1.5OZ (12TU/CS)	All Lots distributed from 12/17/2020 to 07/22/2024	08/01/2024 to 06/01/2028

McKesson Customer Instructions:

1.) Complete the Medical Facility Acknowledgement Form included with this notification and submit it to Integra LifeSciences via fax at 1-609-750-4220 or via email at FCA2@integralife.com.

2.) If you do have units of the impacted product, remove the applicator immediately from service and discard it.

3.) 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.

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.

FIRST NOTIFICATION- URGENT: VOLUNTARY MEDICAL DEVICE CORRECTION

MediHoney® Wound & Burn Dressing Paste
Part#s 31515 and 31535 - For impacted Lot Numbers, see Table 1

September 13, 2024

Dear Valued Integra Customer/Distributor:

This letter serves as notification of a voluntary medical device correction for the MediHoney® Wound & Burn Dressing Paste distributed by Integra LifeSciences due to a potential sterility issue.

Reason for Communication

This voluntary correction has been initiated due to the potential for pinholes in the applicator pouch film (see Figure 1) which creates a sterility concern. The paste is not impacted by this sterility concern. There is no risk to the end user if the applicator is not used to apply the paste directly on the wound. The impacted products are listed in Table 1.

Figure 1: Applicator in Form-Fill-Sealed (FFS) Pouch Film

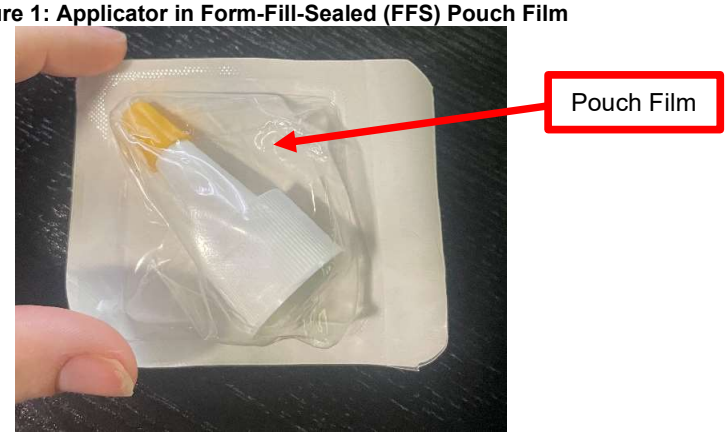

Table 1: Impacted Product Information

Manufacturer's Product Number (Catalog Number)	Product Name (Description)	UDI Number	Lot Number	Expiration Date (MM/DD/YYYY)	Distribution Dates (MM/DD/YYYY)
31515	MEDIHONEY® TUBE - 1.5 FL OZ (44 ML) – W/APPLICATOR-STERILE	10381780486824	All lots distributed from 12/17/2020 to 07/22/2024.	08/01/2024 to 06/01/2028.	12/17/2020 to 07/22/2024
31535	MEDIHONEY® TUBE - 3.5 FL OZ W/APPLICATOR - STERILE	10381780486831			

There have been 4 complaints reported worldwide with the potential to be related to this sterility concern as of August 5, 2024. None of these complaints were serious injury or death reports.

Risk To Health

Based on the health hazard evaluation conducted for this issue, the potential harm is infection if a non-sterile product is used on a patient. There are no long-range health consequences expected due to this issue. If product was used and standard post-operative care is followed, no further patient follow-up is required.

Actions to be Taken by Customers (Medical Facility):

1. Complete the Medical Facility Acknowledgement Form below.
2. If you **do** have units of the impacted product (Table 1) **remove the applicator immediately from service and discard it**.
3. 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.
4. Return the Medical Facility Acknowledgement Form to FCA2@integralife.com or FAX to 1-609-750-4220.
5. Keep a copy of the form for your records.

OR

Actions to be Taken by Distributors:

1. Complete the Distributor Acknowledgement Form below.
2. **Please print and include a copy of this notice with every shipment of impacted products (Table 1) that have not yet been shipped to customers.**
3. Return the Acknowledgement Form to FCA2@integralife.com or FAX to 1-609-750-4220.
4. Keep a copy of the form for your records.
5. **Forward a copy of this notice to any customers that have purchased the impacted products (Table 1).**

Receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. Regulatory agencies such as the FDA perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action.

Should you have any questions regarding these instructions, please contact Customer Service:

Monday to Friday 8:00 AM – 8:00 PM EST
USA: 1-800-654-2873: email: 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)

We apologize for the inconvenience and thank you for your cooperation in this effort.

Sincerely,

Lacey Gigante

Lacey Gigante,
Director, Post-Market Surveillance
Quality Assurance
Integra LifeSciences

URGENT: VOLUNTARY MEDICAL DEVICE CORRECTION

Medical Facility Acknowledgement Form

MediHoney® Wound & Burn Dressing Paste
Part#s 31515 and 31535 - For impacted Lot Numbers, see Table 1

Response is required. Please complete and return promptly.

Please fill out this form and return to:
FCA2@integralife.com or FAX to 1-609-750-4220

Customers (Medical Facility):

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

If yes, please explain: _____

☐ **I do NOT have affected product.**
☐ **I have affected product(s)**. Please complete the questions in the table below.

No.	Instructions	Yes	No
1	I have identified the impacted product(s).	☐	☐
2	I have removed from service and discarded the impacted applicator(s) before use.	☐	☐

_____
Company / Hospital / Medical Facility

_____ _____
Street Address City, Postal Code

_____ _____
Telephone Email

_____ _____
Name (individual completing this form) Title

Entering my name or signing below indicates that I have received, read, and understand the information provided in the Field Notice and have/will comply with the Field Notice and return the completed acknowledgement form.

_____ _____
Name / Signature Date