To the attention of Quality Assurance Dpt or Regulatory Affairs Dpt or Management

Saint Priest, 05 August 2025

URGENT - FIELD SAFETY NOTICE – RECALL

MediHoney® Wound and Burn Products

Legal manufacturer:

DERMA SCIENCES, Inc. 104 Shorting Rd. Toronto, Ontario M1S 3S4

EC Representative:

INTEGRA LIFESCIENCES SERVICES (France) SAS - Immeuble Séquoia 2 - 97 Allée Alexandre Borodine - 69800 SAINT PRIEST, France - SRN : FR-AR-000002474

Impacted Products:

Medical Device	Impacted products (catalog #)	Device Description	Primary Clinical Purpose
MEDIHONEY® WOUND GEL	**391 - 395**	Standardized antibacterial honey, predominantly Leptospermum sp., selected for its unique wound cleaning and antibacterial barrier properties. MediHoney® Antibacterial Wound Gel has been specially formulated combining 80% MediHoney® Antibacterial Honey with natural waxes and oils to provide a high viscosity gel that is easy to apply with good wash off characteristics when dressings are changed.	MediHoney® Wound gel is intended for the management of a wide range of acute and chronic wounds (leg/foot ulcers, pressure ulcers, infected wounds, sloughy wounds, necrotic wounds, malodorous wounds), surgical wounds, donor and recipient graft sites, superficial wounds such as cuts, scratches, abrasions, superficial burns, general first aid
MEDIHONEY® MEDICAL HONEY	**398**	MediHoney® Antibacterial Honey is a standardised antibacterial honey, predominantly Leptospermum sp., selected for its unique wound cleaning and antibacterial barrier properties. MediHoney® Antibacterial Medical Honey™ is a topical preparation which contains 100% MediHoney® Antibacterial Honey	MediHoney® Medical honey is intended for the management of a wide range of acute and chronic wounds (including infected, sinus, deep, sloughy, surgical, necrotic and malodourous wounds), general first aid and superficial burns.
MEDIHONEY® HYDROGEL	**780-781-782-783**	An all-in-one dressing that combines 63% MediHoney® (active Leptospermum) in a hydrogel dressing with a superabsorbent polymer. Available with or without an adhesive border. The adhesive dressing does not require secondary dressing	MediHoney® dressing is indicated for non-draining to slightly exuding wounds such as diabetic foot ulcers, leg ulcers, pressure ulcers / sores, 1st and 2nd degree partial thickness burns, donor sites, traumatic and surgical wounds
MEDIHONEY® HCS BURN DRESSING	**784-785**		
MEDIHONEY® HCS	**787**		
MEDIHONEY® GEL SHEET	**799**		

Dear Valued Integra Distributor,

The purpose of this letter is to advise you that Integra LifeSciences is voluntarily recalling **MediHoney® Wound and Burn** products listed in **Table 1.**

Reason for voluntary recall

Packaging failures were identified related to the MediHoney® Wound and 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 product number in **Table 1,** under 'Issue #'.

The potential issues include:

1. Inadequate sealing of sterile barrier packaging
2. Shipping boxes do not adequately protect device during transportation
3. Tube twist-off cap failure

Risk To Health

Per the Health Hazard Evaluation (HHE) conducted for this issue, the potential harm is infection if a non-sterile product is used on a patient. Additionally, the inability to use the device due to packaging failures may cause inconvenience to the user and prolong/delay the procedure. There are no long-range health consequences expected due to these potential issues.

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.**

As of May 13, 2025, no incidents have been reported in Europe or the United Kingdom.

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

Table 1: Impacted Product Information

Manufacturer's Product Number (Catalog #)	Issue#	Product Name (Description)	UDI Number	Lot Number	Distribution Dates (DD-MM-YY)
391	1,2,3	MEDIHONEY® WOUND GEL, 10 G TUBE – STERILE	N/A	All unexpired lots	21/09/2022 to 27/03/2025
395	1,2,3	MEDIHONEY® WOUND GEL, 20 G TUBE – STERILE	N/A	All unexpired lots	10/02/2023 to 01/04/2025
398	1,2,3	MEDIHONEY® MEDICAL HONEY, 20 G TUBE - STERILE	N/A	All unexpired lots	21 /09/2022 to 18/03/2025
780	2	MEDIHONEY® HYDROGEL 6CM X 6CM SHEET STERILE, 10/BOX X 5...PK:50CS	N/A	All unexpired lots	05/06/2023 to 08/08/2024
781	2	MEDIHONEY® HYDROGEL 11CM X 11CM SHEET STERILE, 10/BOX X 5...PK: 50CS	N/A	All unexpired lots	21/08/2023 to 04/12/2024
782	2	MEDIHONEY® HYDROGEL 7.2CM X 7.2CM ADHESIVE STERILE, 10/BOX X 5...PK:50CS	N/A	All unexpired lots	27/03/2023 to 03/12/2024
783	2	MEDIHONEY® HYDROGEL 11.5CM X 11.5CM ADHESIVE STERILE, 10/BOX X 5...PK:50CS	N/A	All unexpired lots	09/04/2024 to 25/03/2025
784	2	MEDIHONEY® HCS 20CMX20CM BURN DRESSING STERILE, 5/BOX X 4...PK:20CS	N/A	All unexpired lots	11/10/2024 to 24/03/2025

Manufacturer's Product Number (Catalog #)	Issue#	Product Name (Description)	UDI Number	Lot Number	Distribution Dates (DD-MM-YY)
785	2	MEDIHONEY® HCS 20CMX30CM BURN DRESSING STERILE, 2/BOX X 5...PK:10CS	N/A	All unexpired lots	08/05/2024 to 19/03/2025
787	2	MEDIHONEY® HCS 4.5CM X16.5CM STERILE, 2/BOX X 5...PK:10CS	N/A	All unexpired lots	29/03/2023 to 01/04/2025
799	2	MEDIHONEY® GEL SHEET 10CM X 10CM STERILE 1'S, 10/BOX X 10...PK:100CS	N/A	All unexpired lots	09/11/2022 to 05/06/2024

Actions to be taken by Distributors:

1. Please **review and understand** the information provided in this letter.
2. If **you have** affected product(s) in your warehouse:
    a. Quarantine them immediately.
    b. Check the box “I do have affected unit(s)” in the enclosed reply form
    c. Record on the form the total quantity of affected unit(s) and lot number(s) that you have.
3. If **you do not have** affected product(s) in your warehouse**,** check the box, “I do not have affected unit(s)”.
4. Please check **your customer traceability records** for shipments of affected products.
5. **If you have shipped impacted products to your customers, please complete below:**
    a. Create a customer reply form with your contact details.
    b. Forward a copy of the Field Safety Notice to any of your customers that have purchased the affected products and lot numbers.

    Collect completed response forms and affected product(s) from your customers and indicate the total quantities and lot(s) in the distributor reply form (Appendix 1).
6. Please **return the completed and appropriate reply form by email to** emea-fsca@integralife.com,
7. By filling in this form, you confirm that you have received this Safety Notice and you intend to fully comply with this notification. **We expect a response within 21 calendar days from the receipt of this notification.** You also confirm that this notification has been forwarded to every person concerned in your organization.
8. At receipt of your form, and if it is noted that you have affected units available for return, Integra Customer Service will contact you and provide a Return Material Authorization (RMA) number and directions to return the affected product(s). If the products can be discarded, Integra will provide a certificate of destruction for completion.
9. if you do have expired products, quarantine them and discard/destruct following your normal protocol. We recommend that you retain a copy of the form for your records.

PLEASE NOTE THAT REGARDLESS OF WHETHER YOU HAVE THE AFFECTED PRODUCTS TO RETURN OR NOT – **A COMPLETED ACKNOWLEDGEMENT IS REQUIRED**

The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information.

National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Thank you for your cooperation with this Field Safety Corrective Action and for returning the attached Reply Form.

Please feel free to contact our Post Market Surveillance Department at emea-fsca@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Integra LifeSciences Post Marketing Surveillance Department

Appendix 1: Field Safety Notice Reply Form (2 pages)

DISTRIBUTOR/IMPORTER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**2025-HHE-008_011**
FSN Date	**05 August 2025**
Device name	**MediHoney® Wound and Burn products**
Product Code	**391 - 395 - 398 - 780 – 781** **782 - 783 – 784 – 785 - 787 - 799**
Lots	**All unexpired lots**

2. Distributor/Importer Details	
SRN Number	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors/Importers (Tick all that apply)					
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.*				
☐	I have checked my inventory and I <u>have</u> affected units - and I can discard them(1) – enter number of products and lot number (s) (1) *If you choose this option – Integra will provide you with a certificate of destruction upon receipt of the reply form*	**Ref**	**Qty** of unopened or full cases	**Qty of loose units** from opened cases	**Lot number**
☐	I have checked my inventory and I <u>do not</u> have affected products				
☐	I have identified customers that received affected products and informed them of this Field Safety Notice *	*Date of communication:*			
☐	I have attached customer list				
☐	I have received confirmation of reply for all identified customers				

☐	My customers <u>have</u> affected products	**Ref**	**Qty of** unopened or full cases	**Qty of loose units** from opened cases	**Lot number**
☐	My customers have not received any affected products, or all the received products were already consumed				
Print Name*		*Distributor print name here*			
Signature*		*Distributor sign Here*			
Date *					

4. Return acknowledgement to Sender	
Email	emea-fsca@integralife.com
Distributor Helpline	+33 (0) 6 30 20 69 66
Postal Address	Post Market Surveillance Department Integra Immeuble Séquoia 2, 97 allée Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	https://www.integralife.com/
Deadline for returning the distributor reply form*	26/08/2025

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.