To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, 29 December 2025

URGENT - FIELD SAFETY NOTICE – RECALL EXTENSION

Medihoney® Wound and Burn Products

Legal manufacturer:

DERMA SCIENCES, Inc. 104 Shorting Rd. Scarborough, 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:

Product Number (Catalog #)	Device Description	Primary Clinical Purpose
405	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 and can be used for both chronic and acute wound care.	. Sinus wounds . Deep wounds . Infected wounds . Sloughy wounds . Necrotic wounds . Malodorous wounds . Surgical wounds . Superficial wounds such as cuts, scratches, abrasions . Superficial burns . General first aid
793 **794** **795**	MEDIHONEY® Antibacterial Honey Apinate™ Dressing (Apinate™ Dressing) is a sterile, non-adherent wound dressing comprising of calcium alginate fibre impregnated with MEDIHONEY® Antibacterial Honey. The dressing will absorb wound exudate to form a soft gel. The MEDIHONEY® Tulle, Apinate ™ and Gel Sheet Dressings are for use on acute and chronic wounds	. Leg/foot ulcers . Pressure ulcers . Infected wounds . Sloughy wounds . Malodorous wounds . Diabetic wounds . Donor and recipient graft sites . Burns . Superficial wounds such as cuts, scratches, abrasions . Surgical and Necrotic wounds (Tulle and Alginate dressing)
796 **797**	MEDIHONEY® Antibacterial Honey Tulle Dressing (Tulle Dressing) is a sterile, non-adherent, non-absorbent wound dressing comprising of a strong woven dressing impregnated with MEDIHONEY® Antibacterial Honey. The MEDIHONEY® Tulle, Apinate™ and Gel Sheet Dressings are for use on acute and chronic wounds.	

Dear Valued Integra Customer,

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

On August 5, 2025, Integra initiated a voluntary recall of certain MediHoney® Wound and Burn sterile products due to packaging failures that could compromise the sterile barrier. The investigation determined that this potential issue may impact the entire MediHoney® sterile product line. The recall is therefore extended to the entire MediHoney® sterile product range.

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 #)	Product Name (Description)	UDI Number	Lot Number	Distribution Dates (DD-MM-YY)
405	MEDIHONEY MEDICAL HONEY, 50 G TUBE - STERILE	N/A	All unexpired lots	31/03/2023 - 01/04/2025
793	MEDIHONEY ALGINATE ROPE, 1.9 X 30 (CM) X5 BOX - STERILE	N/A		17/05/2023 - 26/03/2025
794	MEDIHONEY ALGINATE DRESSING, 5.1 X5.1(CM) X10 BOX – STERILE	N/A		01/08/2023 - 27/03/2025
795	MEDIHONEY APINATE DRESSING, 10 X 10 (CM) X5 BOX – STERILE	N/A		26/05/2023 – 27-03-2025
796	MEDIHONEY TULLE DRESSING, 10 X 10 (CM) X5 BOX - STERILE	N/A		01/07/2022 - 27/03/2025
797	MEDIHONEY TULLE 3 PLY DRSS, 5 X 5 (CM) X5 BOX - STERILE	N/A		17/05/2022 18/03/2025

Risk To Health

Per the Health Hazard Evaluation conducted for this issue:

- 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.
- There are no long-range health consequences expected due to this issue.
- 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**.

No incident has been reported in Europe

Actions to be taken by Customers:

1. Please **review and understand** the information provided in this letter.
2. If you **have** affected product(s):
    a. Quarantine the units immediately.
    b. Check the box “I do have affected units.” on the enclosed reply form (see Appendix 1).
    c. Record on the form the total quantity of affected products and lot number(s) that you have.
3. If you **do not have** affected product(s), check the box, “I do not have affected units.”

    Please **return the completed and appropriate reply form by email to** emea-fsca@integralife.com. Please be advised that if the products were obtained through a purchasing group or a distributor, you should contact them directly. Kindly avoid using this return address.
4. 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.
5. 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. Integra will issue credit to its direct customer or distributor once returned products or a certificate of destruction have been received and verified.
6. **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.

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)

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	**2025-HHE-015_019**
FSN Date	**29 December 2025**
Product/ Device name	**MediHoney® Wound and Burn products**
Product Code(s)	**405 – 793 – 794 – 795 – 796 – 797**
Lots	**All unexpired lots**

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation					
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.				
☐	I performed all actions requested by the FSN.				
☐	The information and required actions have been brought to the attention of all relevant users and executed.				
☐	I have affected units, and I can discard them(1) – enter product reference, 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 boxes	**Qty of loose units** from opened boxes	**Lot number**

☐	I have affected units available for return - enter product reference, number of products and lot number (s)	**Ref**	**Qty of** unopened or full boxes	**Qty of loose units** from opened boxes	**Lot number**
☐	I do not have any affected units.				
☐	I have a query please contact me				
Print Name*					
Signature*					
Date*					

4. Return acknowledgement to Sender	
Email	emea-fsca@integralife.com
Customer 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 customer reply form*	19/01/2026

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 organisation's reply is the evidence we need to monitor the progress of the corrective action.

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

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Saint Priest, 29 December 2025

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.**

On August 5, 2025, Integra initiated a voluntary recall of certain MediHoney® Wound and Burn sterile products due to packaging failures that could compromise the sterile barrier. The investigation determined that this potential issue may impact the entire MediHoney® sterile product line. The recall is therefore extended to the entire MediHoney® sterile product range.

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Risk To Health

Per the Health Hazard Evaluation conducted for this issue:

- 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.
- There is no long-range health consequences expected due to this issue.
- 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**.

No incident has been reported in Europe.

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 that clearly includes your contact information. End users should be instructed to submit their responses directly to you.**
    b. Forward a copy of the Field Safety Notice to any of your customers that have purchased the affected products and lot numbers.
    c. 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. Integra will issue credit to its direct customer or distributor once returned products or a certificate of destruction have been received and verified.
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**

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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.

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

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DISTRIBUTOR/ *A1 PHARMACEUTICALS PLC* / IMPORTER REPLY FORM

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FSN Reference number	**2025-HHE-015_019**
FSN Date	**29 December 2025**
Device name	**MediHoney® Wound and Burn products**
Product Code	**405 – 793 – 794 – 795 – 796 – 797**
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 box	**Qty of loose units** from opened box	**Lot number**
☐	I <u>have</u> affected units available for return - enter product reference, number of products and lot number (s)	**Ref**	**Qty** of unopened or full box	**Qty of loose units** from opened box	**Lot number**

☐	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 box	**Qty of loose units** from opened box	**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
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