

URGENT - FIELD SAFETY NOTICE – RECALL EXTENSION

COMVITA™ Medihoney® Wound Gel

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

Primary Clinical Purpose

Assist in healing minor burns, cuts, grazes and ulcers

Impacted Products:

MEDIHONEY Antibacterial Wound Gel – 25g tube

MEDIHONEY Antibacterial Wound Gel – 50g tube

Dear Valued Customer,

The purpose of this letter is to inform you that Integra LifeSciences is voluntarily recalling **COMVITA™ MediHoney® Wound Gel** products listed in **Table 1**.

Reason for Recall

Packaging failures were identified related to the MediHoney® Wound and Burn products, which could lead to a breach in the sterile barrier.

Table 1: Impacted Product Information

Product	COMVITA internal reference	CE certificate reference	Batch Number
COMVITA MEDIHONEY ANTIBACTERIAL WOUND GEL 25G	103485	COM389	2326, 2328, 2340, 2341, 2345, 2419, 2429, 2433
COMVITA MEDIHONEY ANTIBACTERIAL WOUND GEL 50G	103486	COM60060	2326, 2332, 2346

Risk To Health

If the packaging of a sterile product is inadequate and the product is used on an open wound, there is a potential risk of infection. Additionally, the inability to use the device due to packaging failures may cause inconvenience to the user and delay care. There is no long-term health consequences expected due to this problem.

No incident has been reported in Europe.

Actions to be taken by Distributors/Retailers

Whether or not you currently hold stock, please take the following action:

- Complete the attached Customer Response Form and return it to Comvita at ahello@comvita.com by 30th April 2026 so we can reconcile as part of the recall process.
- If you have supplied or transferred any potentially affected product to another facility or organisation, provide that facility with a copy of this letter immediately.

If you **do** have affected batches on hand, please **also** take the following action immediately:

- Quarantine any affected stock to prevent further distribution or sale.
- Once we receive your response, we will contact you with next steps, including guidance on the appropriate disposal of any quarantined stock.

Actions to be taken by Consumers:

- Discontinue use of the affected product.
- Contact the Comvita team by emailing hello@comvita.com by the 30th April and we will contact you with next steps,
including guidance on the appropriate disposal of any quarantined stock.

By filling in this form, you confirm that you have received this Safety Notice and you intend to fully comply with this notification. You also are required to confirm that this notification has been forwarded to every person concerned in your organization.

If you do have expired products, quarantine them and discard/destroy 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 National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

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	FSN 2025-HHE- 015 019 COMVITA™ Medihoney®
FSN Date	25 February 2026
Product/ Device name	COMVITA™ MEDIHONEY®
Product Code(s)	103485 (COM389) 103486 (COM60060)
Lots	2326, 2328, 2340, 2341, 2345, 2419, 2429, 2433, 2326, 2332, 2346

2. Customer Details	
Organisation Name	
Organisation Address	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Distributors/Importers (Tick all that apply)					
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content				
<input type="checkbox"/>	I have checked my inventory and I <u>have</u> affected units	Ref	Qty of unopened or full box	Qty of loose units from opened box	Lot number
<input type="checkbox"/>	I have identified customers that received affected products and informed them of this Field Safety Notice	<i>Date of communication:</i>			
<input type="checkbox"/>	I have attached customer list				
<input type="checkbox"/>	I have received confirmation of reply for all identified customers				
<input type="checkbox"/>	My customers <u>have</u> affected products	Ref	Qty of unopened or full box	Qty of loose units from opened box	Lot number

<input type="checkbox"/>	My customers have not received any affected products, or all the received products were already consumed				
Print Name		<i>Distributor print name here</i>			
Signature		<i>Distributor sign Here</i>			
Date					