

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

January 08, 2025

URGENT - FIELD SAFETY NOTICE – INTEGRA – RECALL
MediHoney® Barrier and Derma non-sterile creams

Legal manufacturer:

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

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
597	MediHoney® Derma Cream helps protect vulnerable skin. It can be used on large skin areas and under compression or wound dressings to protect intact skin from breakdown and irritation caused by dryness, friction or shear. It also helps moisturize dry skin.	<ul style="list-style-type: none"> • Protects intact, vulnerable or at-risk skin from breakdown • Helps maintain the skin's barrier properties and maintain skin moisture • Helps protect the skin from irritation or breakdown caused by dryness, friction or shear • Helps reduce itching
582 800	MediHoney® Barrier Cream can be applied to intact and at-risk skin to provide protection from body fluids and moisture. It can be applied around wounds and under skin folds where a protective barrier will help prevent skin breakdown. The cream can also be applied under wound dressings and incontinence pads where the skin can be at-risk of damage. MediHoney® Barrier Cream helps maintain the skin's barrier properties and maintain skin moisture.	<ul style="list-style-type: none"> • Protects at-risk skin from breakdown associated with incontinence and can be used under incontinence pads • Can be used around wound edges to protect the skin from irritation or breakdown caused by wound exudate • Helps protect the skin from damage caused by friction or shear • Helps prevent maceration • Helps prevent excoriation • Helps prevent damage to skin caused by frequent hand washing

LOT NUMBERS: all lot numbers are affected by this recall

Dear Valued Integra Distributor,

The purpose of this letter is to advise you that Integra LifeSciences is voluntarily recalling **MediHoney® Barrier and Derma non-sterile products** listed in Table 1.

During an investigation, Integra LifeSciences identified inadequately good manufacturing processes related to the production of non-sterile Barrier and Derma creams.

A total of three (3) complaints has occurred in Europe with skin reaction. No serious injury has been reported in Europe. No other complaint has been recorded Worldwide.

Table 1 summarizes the impacted products in this communication.

Table 1: Impacted Product Information

Manufacturer's Product Number (Catalog #)	Product Name (Description)	UDI Number	Lot Number
582	MEDIHONEY BARRIER CREAM 50 G TUBE, 1 TUBE/CTN X 24...PK:24/CS	N/A	All unexpired lots
597	MEDIHONEY DERMA CREAM 50 G TUBE, 1 TUBE/CTN X 24...PK:24/CS	N/A	
800	MEDIHONEY BARRIER CREAM 2 GRAM SACHET, 20/BX X 10...PK:200/CS	N/A	

This recall is in addition to all MediHoney® products that have been previously recalled. This recall applies only to products that are unexpired. If you have expired products, please ensure that you discard them per your facility's policies and procedures.

Risks to Health

Per the Health Hazard Evaluation (HHE), if the MediHoney is contaminated and used on a patient it may have an immediate harm of skin Inflammation, irritation or an allergic reaction. There are no long-range health consequences.

If you have already used the products affected by this recall and the product instructions were followed, there is no additional customer follow-up or medical intervention required.

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**.

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.

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 customers or distributors only once returned products or a certificate of destruction have been received and verified.

We recommend that you retain a copy of the form for your records.

PLEASE NOTE THAT WHETHER YOU HAVE AFFECTED PRODUCT 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)

DISTRIBUTOR/IMPORTER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	2025-HHE-020
Date FSN	08/01/2026
Device name	MediHoney® Barrier and Derma non-sterile creams
Product Code	582 – 597 – 800
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)					
<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 - and I can discard them ⁽¹⁾ – enter number of products and lot number (s) <i>(¹ If you choose this option – Integra will provide you with a certificate of destruction upon receipt of the reply form)</i>	Ref	Qty of unopened or full boxes (Individual tube or pouch must be reported as loose units)	Qty of loose units from opened boxes	Lot number
<input type="checkbox"/>	I have affected units available for return - enter product reference, number of products and lot number (s)	Ref	Qty of unopened or full boxes (Individual tube or pouch must be reported as loose units)	Qty of loose units from opened boxes	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 boxes (Individual tube or pouch must be reported as loose units)	Qty of loose units from opened boxes	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 *					

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*	02/02/2026

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

To the attention of Medical Device Vigilance
responsible / Central Pharmacy

January 8, 2025

URGENT - FIELD SAFETY NOTICE – INTEGRA – RECALL
MediHoney® Barrier and Derma non-sterile creams

Legal manufacturer: DERMA SCIENCES, Inc. 104 Shorting Rd. Scarborough, Ontario M1S 3S4, Canada

EC Representative:

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Impacted products:

Product Number (Catalog #)	Device Description	Primary Clinical Purpose
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582 800	MediHoney® Barrier Cream can be applied to intact and at-risk skin to provide protection from body fluids and moisture. It can be applied around wounds and under skin folds where a protective barrier will help prevent skin breakdown. The cream can also be applied under wound dressings and incontinence pads where the skin can be at-risk of damage. MediHoney® Barrier Cream helps maintain the skin's barrier properties and maintain skin moisture.	<ul style="list-style-type: none"> • Protects at-risk skin from breakdown associated with incontinence and can be used under incontinence pads • Can be used around wound edges to protect the skin from irritation or breakdown caused by wound exudate • Helps protect the skin from damage caused by friction or shear • Helps prevent maceration • Helps prevent excoriation • Helps prevent damage to skin caused by frequent hand washing

LOT NUMBERS: all lot numbers are affected by this recall

Dear Valued Integra Customer,

The purpose of this letter is to advise you that Integra LifeSciences is voluntarily recalling **MediHoney® Barrier and Derma non-sterile products** listed in Table 1.

During an investigation, Integra LifeSciences identified inadequately good manufacturing processes related to the production of non-sterile Barrier and Derma creams.

A total of three (3) complaints has occurred in Europe with skin reaction. No serious injury has been reported in Europe. No other complaint has been recorded Worldwide.

Table 1 summarizes the impacted products in this communication.

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This recall is in addition to all MediHoney® products that have been previously recalled. This recall applies only to products that are unexpired. If you have expired products, please ensure that you discard them per your facility's policies and procedures.

Risks to Health

Per the Health Hazard Evaluation (HHE), if the Medihoney is contaminated and used on a patient it may have an immediate harm of skin Inflammation, irritation or an allergic reaction. There are no long-range health consequences.

If you have already used the products affected by this recall and the product instructions were followed, there is no additional customer follow-up or medical intervention required.

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. Do not continue to use the product(s) and quarantine the unit(s) 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."
4. Please **return the completed and appropriate reply form by email to emea-fsca@integralife.com. If the products were obtained through a purchasing group or a distributor, please reach out to them directly. We kindly ask that you do not use this Integra email address.**

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.

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 customers or distributors only once returned products or a certificate of destruction have been received and verified.

We recommend that you retain a copy of the form for your records.

PLEASE NOTE THAT WHETHER YOU HAVE AFFECTED PRODUCT 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-020
Date FSN	08/01/2026
Product/ Device name	MediHoney® Barrier and Derma non-sterile creams
Product Code(s)	582 – 597 – 800
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					
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.				
<input type="checkbox"/>	I performed all actions requested by the FSN.				
<input type="checkbox"/>	The information and required actions have been brought to the attention of all relevant users and executed.				
<input type="checkbox"/>	I have affected units, and I can discard them ⁽¹⁾ – enter product reference, number of products and lot number (s) <i>(¹ If you choose this option – Integra will provide you with a certificate of destruction upon receipt of the reply form)</i>	Ref	Qty of unopened or full boxes <i>(Individual tube or pouch must be reported as loose units)</i>	Qty of loose units from opened boxes	Lot number

<input type="checkbox"/> 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 boxes <i>(Individual tube or pouch must be reported as loose units)</i>	Qty of loose units from opened boxes	Lot number
<input type="checkbox"/> I <u>do not</u> have any affected units.				
<input type="checkbox"/> 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
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Your organisation's reply is the evidence we need to monitor the progress of the corrective action.