To the attention of Medical Device Vigilance responsible / Central Pharmacy / BioMedical Engineer

INTEGRA
LIMIT UNCERTAINTY

Saint Priest, March 16, 2015

Subject: **URGENT – FIELD SAFETY NOTICE – RECALL**
Medical devices: **Integra® Flowable Wound Matrix**
Reference: FDR301
Legal Manufacturer: Integra Life Sciences Corporation - 311 Enterprise Drive - Plainsboro, NJ 08536, USA
Affected lot number: 305000298616

Dear Customer,

Integra LifeSciences has identified through an internal investigation there is a possibility that one lot of our Integra® Flowable Wound Matrix may not meet the criteria for proper mixing that is listed in the product Instructions for Use.

Integra Flowable Wound Matrix is an advanced wound care device comprised of a granulated form of the Integra Dermal Regeneration Template – Single Layer. It is indicated for the treatment of tunneling and/or undermined wounds including: surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence) and diabetic ulcers of both partial and full-thickness varieties.

There has not been any report of a patient injury or adverse health consequences as a result of this concern and Integra's investigation indicates that although not appearing to be properly mixed, the product performs as it should when used. Out of an abundance of caution, Integra is voluntary recalling these specific lot number of Integra® Flowable Wound Matrix.

Description of affected product	Reference	Affected Lot Number
Integra® Flowable Wound Matrix	FDR301	**305000298616**

Our records indicate that you received one or more Integra® Flowable Wound Matrix affected.

Integra kindly asks you to examine your inventory to determine if you have these devices.

Once the audit of your inventory achieved, please stop using them immediately and remove them from service and to quarantine them.

Then, please complete the attached Recall Acknowledgement and Return Form and return it promptly as per the instructions on the form.

Once your Recall Acknowledgement and Return Form is received and if you have identified affected product(s), our Customer Service will contact you and provide an RMA number and instructions for returning the product(s).

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

We also recommend that you keep a copy of this notification and a signed copy of the acknowledgement form for your records.

National Competent Authorities may perform audits of field actions of this nature to verify that our

Integra LifeSciences Services (France)
Siège Social : Immeuble Séquoia 2 ▪ 97 allée Alexandre Borodine ▪ Parc Technologique de la Porte des Alpes ▪ 69800 Saint Priest ▪ France
33 (0)4 37 47 59 00 office ▪ 33 (0)4 37 47 59 99 fax ▪ integralife.com
Société par Actions Simplifiée au capital de 37.000 € ▪ NAF 4646Z ▪ 492 534 466 RCS Lyon
Deutsche Bank AG Paris FR76 1778 9000 0110 5107 2400 081 DEUTFRPP ▪ No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466

customers have been notified and understand the nature of the field action being taken.

Please note that your National Competent Authority 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 Recall Acknowledgement and Return Form.

For any questions or concerns, please contact the following e-mail address: EMEAFSCAOTTS&W@integralife.com.

Sincerely,

Angélique AUBERT
Compliance coordinator
Europe, Middle-East & Africa

Enclosed: Recall Acknowledgment and Return Form

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RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical devices: **Integra® Flowable Wound Matrix**
Reference: FDR301
Legal Manufacturer: Integra LifeSciences Corporation - 311 Enterprise Drive - Plainsboro, NJ 08536, USA
Affected lot numbers: 305000298616

Please Complete and Return Promptly

Please fill out this form and return by email or fax:
By fax/telecopy: **+33 (0)4 37 47 59 30** or by e-mail: EMEAFSCAOTTS&W@integralife.com

I have received, read and understood the information provided in the Integra Field Safety Notice regarding **Integra® Flowable Wound Matrix.**

My inventory has been reviewed and the results are as follow (*please tick the appropriate answer*):

☐ **Yes**, I do have affected product(s) in my inventory.
Please fill out in the table below:

Description of affected product	Reference	Affected Lot Number	Quantity
Integra® Flowable Wound Matrix	FDR301	305000298616	

☐ **No**, I do not have the affected product in my inventory.

With this form,
- I confirm that I have received this Field Safety Notice – recall – and that I intend to fully comply with it;
- I confirm that this Field Safety Notice – recall – has been circulated to all affected users. They have been asked to discontinue the use of the affected products and to remove them from service;
- I ensure that all the affected products will be returned to Integra.

Please complete contact point details below.

Customer/Site Name _____ Customer Contact Name _____

Street Address _____

City, Country, Postal Code _____ Telephone _____

Email _____

Fax _____ Signature _____

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