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

Saint Priest, 17/12/2019

Subject: **URGENT - FIELD SAFETY NOTICE** – IDRT TS, IDRT MESHED and IDRT SINGLE LAYER– IFU missing pages

Legal manufacturer:

Integra LifeSciences; 105 Morgan Lane; Plainsboro, NJ 08536, USA

EC Rep:

INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoïa 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST

Medical devices:

INTEGRA Dermal Regeneration Template is a bilayer membrane system for skin replacement. The dermal replacement layer is made of a porous matrix of fibers of cross-linked bovine tendon collagen and a glycosaminoglycan (chondroitin-6-sulfate) that is manufactured with a controlled porosity and defined degradation rate. The epidermal substitute layer is made of a thin polysiloxane (silicone) layer to control moisture loss from the wound.
INTEGRA Dermal Regeneration Template Single Layer consists only of the dermal regeneration layer and is available to add extra thickness to the dermal regeneration layer, when deep wounds are to be treated.
INTEGRA® Dermal Regeneration Template (Integra Template) is available in Meshed and Non-Meshed configurations.
INTEGRA template is provided sterile. The inner foil pouch and product should be handled using sterile technique. INTEGRA template should not be re-sterilized.

Primary clinical purpose of device(s):

INTEGRA Dermal Regeneration Template is indicated for the postexcisional treatment of full-thickness and partial-thickness injuries where sufficient autograft is not available at the time of excision or not desirable due to the physiological condition of the patient. INTEGRA Dermal Regeneration Template is also indicated for use in reconstruction of postexcisional, full-thickness defects of the integument where there is, in the opinion of the treating surgeon, a potential benefit to the patient by improving the reconstructive outcome or decreasing their mortality/morbidity.

Concerned references and batches:

Listed in Attachment 1

Dear Valued Customer,

The purpose of this letter is to notify you that the legal manufacturer Integra LifeSciences, is voluntarily issuing a Field Safety Notice for the IDRT-TS, IDRT MESHED and IDRT SINGLE LAYER for the part numbers and lots listed in Attachment 1.

During the packaging process of IDRT-TS, IDRT MESHED and IDRT SINGLE LAYER, it was identified that one Instruction for Use (IFU) insert was missing pages with some languages. A 100% inspection was performed, and additional defects were identified including blank pages, missing pages, for all languages except English.

The assessment completed by the legal manufacturer Integra LifeSciences, concluded that the missing pages in IFU's presents an inconvenience to user. The assessment also concluded graft failure could occur in the highlty unlikely scenario that the graft is implanted without removing the silicone layer placed on the graft for packaging.
The risks mentioned above have been assessed based on standard ISO 14971 and other applicable regulations listed in our internal procedures.

We are notifying you of the Field Safety Corrective Action as our records indicate that you have been supplied with concerned products listed in attachment 1.

To mitigate the risk, we kindly ask you to refer to the Instructions For Use (IFU) on the Integra website. For your convenience, the fully tranlated IFUs are posted in the following link:

http://app.sales.integralife.com/tissue-technologies/integra-dermal-regeneration-template-idrt/regulatory/integra-dermal-regeneration-template-single-layer-and-single-layer-thin-ifu.pdf

http://app.sales.integralife.com/tissue-technologies/integra-dermal-regeneration-template-idrt/regulatory/integra-dermal-regeneration-template-and-integra-meshed-dermal-regeneration-template-ifu.pdf

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially concerned devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer reply is required. A form is attached to this Field Safery Notice. The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. We expect a response **within 3 weeks**.

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 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 me for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Angelique AUBERT
EMEA Compliance Coordinator

Enclosed: Field Safety Notice Customer Reply Form (2 pages), Attachment 1

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-HHE-161-061219B
FSN Date*	17/12/2019
Product/ Device name*	IDRT TS, IDRT MECHED and IDRT SINGLE LAYER– IFU
Product Code(s)	Listed in Attachment 1
Batch/Serial Number (s)	Listed in Attachment 1

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

3. Return acknowledgement to Sender	
Email	emea-fsca-recon@integralife.com
Distributor Helpline	+33 (0) 4 37 47 59 16
Postal Address	Integra Regulatory Affairs • Immeuble Séquoia 2, 97 allées Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	www.integralife.com
Deadline for returning the Distributor reply form*	20th of January 2020

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	

☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor print name here
Signature*		Distributor sign Here
Date *		

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 actions.

ATTACHMENT 1

SKU	Description	Lot #	IFU N°
62021	IDRT - Single Layer 5 cm x 5 cm	4162437	Integra® Dermal Regeneration Template Single Layer Integra® Dermal Regeneration Template Single Layer (Thin) N°:6200020050 Rev.02 10/17 0554621-1
82021	Integra® Dermal Regeneration Template-TS 5 cm x 5 cm	4176104	Integra® Dermal Regeneration Template Integra® Meshed Dermal Regeneration Template No: 7500010000 Rev. 01 02/18 0583276-4
84051	Integra® Dermal Regeneration Template-TS 10 cm x 12.5 cm	4176091	
88101	Integra® Meshed Dermal Regeneration Template-TS 20 cm x 25 cm	4189619	