INTEGRA'I

LIMIT UNCERTAINTY .

To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, 08/04/19

Subject: **URGENT- FIELD SAFETY NOTICE** - **SAFETY INFORMATION**

Medica! devices: ***Integra® MGT-890-10MT*** - ***MGT Movement Metatarsal Sz. 10; MGT-890-20MT*** - ***MGT Movement Metatarsal Sz. 20; MGT-890-30MT*** - ***MGT Movement Metatarsal Sz. 30; MGT-890-40MT*** - ***MGT Movement Metatarsal Sz. 40***

Legal manufacturer: *Ascension Orthopedics, Ine. - 11101 Metric Blvd, Austin, Texas 78758 USA*

EG Rep: *INTEGRA L/FESCIENCES (France)* SAS- *lmmeuble Séquoïa 2- 97 Allée Alexandre Borodine - 69800 SAINT PR/EST*

Concerned batches:

All lots sold between 2013 - today

Dear Valued Customer,

lntegra LifeSciences has recently identified a contradiction between the IFU and the European Middle East Africa surgical technique of lntegra® Movement™ Great Toe System, concerning the use of the cement for the total-arthroplasty procedures.

Two procedures are indicated for the lntegra Movement Great Toe System (IFU LC-04-890-005 Rev G)
"Hemi-Arthrop/asty:
The lntegra Movement Great Toe System hemi arthroplasty consists of a *metatarsal component and* a *phalengeal component designed for resurfacing the 1st metatarsal head or the base of the proximal phalanx. The metatarsa/ and phalangeal components are used* as *hemi-arthroplasties as an uncemented joint treatment of patients with arthritis in the first metatarsal joint in the presence of good bone stock. Indications include:*
• Hallux valgus or Hallux limitus
• Hallux rigidus
• Unstable or painful metatarsal!phalangea/ (MTP) joint
Total Arthroplastv
The lntegra Movement Great Toe System *total arthroplasty is* a *two-piece implant that is intended to be used* as *prosthesis for the metatarso-phalangea/ joint (MTP).* ***The device is intended for cemented use only.*** *Indications for use include:*
• Painful degenerative metatarso-phalangea/ joint change
• Hallux rigidus stage 3 and 4
• Hallux valgus and hallux rigidus
• Hallux limitus with painful arthrofibrosis
• Revisions after moderate proximal phalanx resection"

Consequently, out of abundance of caution and to ensure patient safety, the legal manufacturer Ascension Orthopedics Ine, has updated the lntegra® Movement™ Great Toe System European Middle East Africa Surgical Technique LC-04-890-006 Rev B (Attachment 1). The following sections of the Surgical Technique have been revised to contain additional language and more specific instructions on the proper technique:
Total Great Toe Surgical Technique page 12

We are notifying you of this Field Safety Notice as our records indicate that you have been supplied with **devices listed below.**

Integra LifeSciences Services (France)
Siège Social : lmmeuble Séquoia 2 • 97 allée Alexandre Borodine • Pare Technologique de la Porte des Alpes • 69800 Saint Priest • France
33 (0)4 37 47 59 oo 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 BankAG Paris FR761778 90000110 5107 2400081 DEUTFRPP. No TVA Intracommunautaire/ I.VA T. : FR 82 492 534466

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Description of affected produc	Reference
MGT Movement Metatarsal Sz. 10	**MGT-890-1OMT**
MGT Movement Metatarsal Sz. 20	**MGT-890-20MT**
MGT Movement Metatarsal Sz. 30	**MGT-890-30MT**
MGT Movement Metatarsal Sz. 40	**MGT-890-40MT**

Please ensure that this Field Safety Notice and the Attachment is provided to every concerned user of Integra® Movement™ Great Toe System.

Additionally, please sign and return the "aknowledgement and return form" enclosed, by which you confirm that you have received this Field Safety Notice and you intend to fully comply with. You also confirm that this notification has been forwarded to every concerned users.

The receipt of this form ensures that Integra has achieved alevel 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.

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 Acknowledgement and Return Form.

For any questions or concerns, please contact us at the following e-mail address: emea-fsca-recon@integralife.com

Sincerely,

Compliance Coordinator
Europe, Middle-East & Africa

Enclosed: Acknowledgement and Return Form (1 page)+ Attachment1 Surgical Technique

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ACKNOWLEDGEMENTFORM

Medical devices:

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Legal manufacturer:

Ascension Orthopedics, Ine. - 11101 Metric 8 lvd, Austin, Texas 78758 USA

EC Rep: *INTEGRA LIFESCIENCES (France) SAS- Immeuble Séquoïa 2- 97 Allée A/exandre Borodine - 69800 SAINT PR/EST*

Concerned batches:

A/1 /ots so/d between 2013 - today

March 2019

Please send the form back to:

By fax/telecopy: +33 (0)4 37 47 59 30

Or by e-mail: emea-fsca-recon@integraJi fe .com

With this form, 1 confirm that:

1 have received, read and understood the information provided in the lntegra Field Safety Notice notification regarding lntegra® Movement™ Great Toe System.

1 confirm that this Field Safety Notice and the Attachment have been circulated to all affected users.

Customer Name	Date
Street Address	City/State/Zip Code
Telephone Number	Signature

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