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

Saint Priest, 31/05/18

Subject: **URGENT - FIELD SAFETY NOTICE - RECALL NOTIFICATION LETTER**

Medical devices:
HINTEGRA® Screws and HINTEGRA® SENSITIVE Screws - Sterile
Reference: ***HINTEGRA®****: 303312S; 303316S; 303320S; 303328S; 303330S; 303334S; 303338S; 303340S; 303342S.*
HINTEGRA® SENSITIVE*: 303512S; 303516S; 303520S; 303530S; 303534S; 303538S; 303540S; 303542S.*
Legal manufacturer:
Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.
Concerned batches:
All non-expired and unused products – Listed in annex 1

Dear Valued Customer,

Newdeal SAS, a company of Integra LifeSciences, has identified, through an internal evaluation, the possibility of sealing defect for HINTEGRA® Screws and HINTEGRA® SENSITIVE Screws packaging. The defect is a non-homogeneous seal or insufficient sealing width and if it were not completely sealed, the sterility of the packaging or the device itself could be compromised.

Loss of sterility may result in a wound infection that is significant but reversible, requiring intervention beyond standard-of-care. The package defect might not be easily detectable upon visual inspection prior to use but an adverse health consequence is unlikely to occur based on our health hazard evaluation.

The review of the available clinical data on the plates HINTEGRA® Screws and HINTEGRA® SENSITIVE Screws does not raise an abnormal infection rate, consequently no specific follow up for patient implanted is required.

We are notifying you of this recall as our records indicate that you have been supplied with **devices listed in annex 1.**

We kindly ask you to examine your inventory to determine if you have affected devices listed in annex 1, please quarantine them.

We also kindly ask you to contact the final customers who may have the affected products and provide them with this letter. If they have affected product, they have to stop using them immediately and remove them from service.

Once the audit of your inventory and your final customers' inventory achieved, please sign and return the "Recall acknowledgment and Return Form" enclosed, by which you confirm that you have received this Recall notification and you intend to fully comply with this Recall notification.

With this form, you will ensure that all the devices affected will be sent back including those already shipped to your customers. You also confirm that this notification has been forwarded to every concerned customer.

Integra Customer Service will contact you upon receipt of this information to organize the return of the concerned products (Return Merchandise Authorization number assignment).

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

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

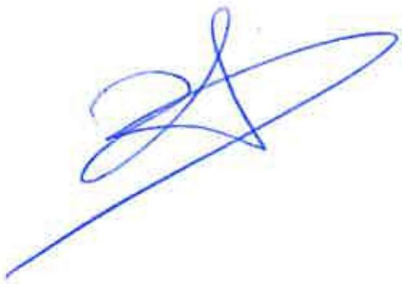
We also recommend that you keep a copy of this notification and a signed copy of the acknowledgement form for your records.

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,



Angélique Aubert
Compliance coordinator
Europe, Middle-East & Africa

Enclosed: Recall Acknowledgment and Return Form (1 page)
Annex 1 (5 pages)

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RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical devices:

HINTEGRA® Screws and HINTEGRA® SENSITIVE Screws - Sterile

Reference: ***HINTEGRA®****: 303312S; 303316S; 303320S; 303328S; 303330S; 303334S; 303338S; 303340S; 303342S.*

HINTEGRA® SENSITIVE*: 303512S; 303516S; 303520S; 303530S; 303534S; 303538S; 303540S; 303542S.*

Legal manufacturer:

Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.

Concerned batches:

All non-expired and unused products listed in the annex 1

May 2018

Please send the form back to:

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

Or by e-mail: *emea-fsca-recon@integralife.com*

With this form, I confirm that:

I have received, read and understood the information provided in the Integra Recall notification regarding plates HINTEGRA® Screws and HINTEGRA® SENSITIVE Screws.

I have transferred this recall letter to the persons to whom I have sold and/or place on consignment the concerned products. I ensure that the form is duly returned to me signed by these persons.

I ensure that all the affected products, including those I had already sent to my customers are being quarantined and will be shipped back to Integra.

My inventory and my final customers' inventory have been reviewed and the results are as follow (*please tick the appropriate answer*):

☐ **Yes**, I do have affected product(s) in my inventory or my final customers' inventory. These affected product(s) have been isolated and will be sent back.

Please indicate quantity and lot numbers in Annex 1.

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

Distributor / Healthcare facility name

Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Signature

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Annex 1

Description of affected product	Reference	Affected Lot Number	Qty
HINTEGRA® *Screws*	303312S	EDMQ/1 - ENAF - EQ0Y - EQ13 – FDCH - FEFW - FGKP - FH2L - FJ1D	
	303316S	FDNR - FED5 - FGAY - FJ1E	
	303320S	EQ0Z/1 - FC1R-FDNS - FED6 - FGAZ - FGKQ - FJ1F - FJDC - FK73	
	303328S	F8XW - F94N - F94P-F94Q - F94R - F9JW - F9JW/S - F9QU - FDCJ - FDNT - FED7 - FGB0 - FGKR - FJ1G - FK74 - FK9W	
	303330S	EEJE/1 - EJBL/1 - ENAG/1 - F7BX- F9HR-FDNU - FED8 - FGKM - FJ1H - FJDD - FK9V	
	303334S	ENAK/1 - FA9F – FDCK - FED9	
	303338S	ENAB – EPPY - EQ11 - EQ17	
	303340S	ENAD/1 - EQ19 - FH2N - FJ1J - FJDE	
	303342S	EDAN/1 - EHKA/1 - EJXG/1 - F94S - FAYY-FCBC – FEDA - FGB1 - FGKS - FH2P - FJDF	
HINTEGRA® SENSITIVE *Screws*	303512S	ENY4	
	303516S	EH5Y/G	
	303520S	ENY5 - F0FU - F0FU/S	
	303530S	EFJ5 - EFJ6 - EFJ6/S	
	303534S	FAEC - FEDB	
	303538S	FAED - FEDC	
	303540S	FAEE - FEDD	
	303542S	FAEF - FEDE	

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