INTEGRA
LIMIT UNCERTAINTY

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

Saint Priest, May 17th 2018

Sujet: **URGENT – FIELD SAFETY NOTICE – RECALL NOTIFICATION LETTER**
Medical device:
HINTEGRA® Screws and HINTEGRA® SENSITIVE Screws - Sterile
Reference:
See list of references in attachment 1
Legal Manufacturer :
NEWDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest – France.
Batch involved:
All non-expired and unused products listed on Appendix 1

Madam, Sir,

Newdeal SAS, a company within Integra LifeSciences Group, has recently identified, through an internal evaluation, the possibility of sealing defect for the HINTEGRA® screws and HINTEGRA® SENSITIVE screws packaging. The defect is a non-homogeneous seal or an insufficient sealing width and if it were not completely sealed, the sterility of the packaging or the screw 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. While an adverse health consequence is unlikely to occur based on our health hazard evaluation, Newdeal SAS has made the decision to conduct a voluntary recall of any unused and unexpired products listed on appendix 1.

The review of the available clinical data on the 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 the recall as our records indicate that you have been supplied with some devices listed on appendix 1.

We kindly ask you to examine your inventory to determine if you have devices listed on appendix 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 HINTEGRA® screws and HINTEGRA® SENSITIVE screws 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.

Newdeal
Siège Social : Immeuble Séquoia 2 ▪ 97 allée Alexandre Borodine ▪ Parc Technologique de la Porte des Alpes ▪
69800 Saint Priest ▪ France
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Integra Customer Service will contact you upon receipt of this information to organize the return of the concerned products (Return Merchandise Authorization number assignment).

The receipt of this form ensures that Newdeal 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,

Marilyse Latour
NEWDEAL SAS
Quality Assurance and Regulatory Affairs Manager

In attached file: Recall acknowledgment and Return Form (2 pages)
Appendix 1 – List of references and batches involved (1 page)

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RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical device:
HINTEGRA® screws and HINTEGRA® SENSITIVE screws - Sterile
Reference:
See the list of references in attachment 1

Legal Manufacturer :
NEWDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest – France.
Batch involved:
All non-expired and unused products listed on Attachment 1
May 2018

Please send the form back to:

By fax/telecopy: +33 (0)4 37 47 51 52
Or by e-mail: marilyse.latour@integralife.com

With this form, I confirm that:

I have received, read and understood the information provided in the Integra Recall notification regarding the 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.

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, lot numbers and circle the reference involved in the table below:

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

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.

Distributor / Healthcare facility name Contact Name

Street Address

City, Country, Postal Code Telephone

Email Signature

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Batch involved:

All non-expired and unused products listed on Attachment 1

May 2018

Reference	Affected batch	Quantity

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APPENDIX 1 – List of references and batches involved by the recall

Reference	Lot
303312SND	EDMQ/1
303312SND	ENAF
303312SND	EQ0Y
303312SND	EQ13
303312SND	FDCH
303312SND	FEFW
303316SND	FDNR
303316SND	FED5
303316SND	FGAY
303320SND	EQ0Z/1
303320SND	FC1R
303320SND	FDNS
303320SND	FED6
303320SND	FGAZ
303320SND	FGKQ
303328SND	F8XW
303328SND	F94N
303328SND	F94P
303328SND	F94Q
303328SND	F94R
303328SND	F9JW
303328SND	F9JW/S
303328SND	F9QU
303328SND	FDCJ
303328SND	FDNT
303328SND	FED7
303328SND	FGB0
303328SND	FGKR
303330SND	EEJE/1
303330SND	EJBL/1
303330SND	ENAG/1
303330SND	F7BX

Reference	Lot
303330SND	F9HR
303330SND	FDNU
303330SND	FED8
303330SND	FGKM
303334SND	ENAK/1
303334SND	FA9F
303334SND	FDCK
303334SND	FED9
303338SND	ENAB
303338SND	EPPY
303338SND	EQ11
303338SND	EQ17
303340SND	ENAD/1
303340SND	EQ19
303340SND	FH2N
303342SND	EDAN/1
303342SND	EHKA/1
303342SND	EJXG/1
303342SND	F94S
303342SND	FAYY
303342SND	FCBC
303342SND	FEDA
303342SND	FGB1
303512SND	ENY4
303516SND	EH5Y/G
303520SND	ENY5
303530SND	EFJ5
303534SND	FAEC
303538SND	FAED
303540SND	FAEE
303540SND	FEDD
303542SND	FAEF

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