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

INTEGRA
LIMIT UNCERTAINTY

Distributor Integra

Saint-Priest, March 5th 2014

Object: **URGENT - FIELD SAFETY NOTICE – INSPECTION PROCESS**

Medical devices:
HINTEGRA® TOTAL ANKLE PROSTHESIS Standard tibial and talar components
HINTEGRA® TOTAL ANKLE PROSTHESIS Sensitive tibial and talar components
HINTEGRA® TOTAL ANKLE PROSTHESIS Revision tibial and talar components
HINTEGRA® TOTAL ANKLE PROSTHESIS Sensitive revision tibial and talar components
References: See APPENDIX A

Legal Manufacturer : NEWDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest – France.

Concerned batches: All non expired products.

Madam, Sir,

Newdeal SAS, a company within Integra LifeSciences Group, has recently identified, through an internal evaluation, a risk of damage to the package (external pouch) of the Hintegra® total ankle prosthesis tibial and talar components during shipping/handling. This damage might lead to a breakage of the sterility barrier of this external pouch, thus posing the risk of a potential patient infection. The risk for an adverse patient consequence has been determined to be not likely based onto our health hazard evaluation.
The review of the available clinical data on the Hintegra® prosthesis does not raise an abnormal infection rate, consequently no specific follow up for patient implanted is required.

We are notifying you of this field safety notice as our records indicate that you have been supplied with Hintegra® total ankle prosthesis tibial and talar components.

Internal investigation has confirmed that not all Hintegra® total ankle prosthesis tibial and talar components are affected. Consequently, Newdeal SAS has made the decision to have Integra trained representatives perform an inspection of the Hintegra® total ankle prosthesis tibial and talar components at the healthcare facility before each surgery by following the inspection process enclosed that has been verified as effective. The inspection process will assure that only products without damaged external pouches are used in surgeries.

Any of the products listed in appendix A must not be used without this inspection process.

If any Hintegra® total ankle prosthesis tibial and talar component packaging is damaged, the device will be segregated to prevent its use and the Integra trained Representatives will ship them back to Newdeal for exchange. Newdeal SAS will bear the costs of the products exchanged and related transport.
For this purpose, after having performed the inspection, the Integra trained Representatives will contact the Integra Customer Service to organize the return and exchange of the damaged products (Return Merchandise Authorization number assignment as well as return instruction).

Please sign and return the "Field Safety Notice Acknowledgment and Return Form" enclosed, by which you confirm that you have received this notification and you intend to fully comply with this notification.

With this form, you will ensure that a Integra trained Representative will attend each Hintegra® Prosthesis surgery in order to perform the inspection. And you confirm that this notification has been circulated to all concerned users / customers.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Newdeal
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 51 51 office ▪ 33 (0)4 37 47 51 52 fax ▪ integralife.com
Société par Actions Simplifiée au capital de 1.000.000 € ▪ NAF 4646Z ▪ 412 111 510 RCS Lyon

Your cooperation is appreciated, and we thank you for your continued collaboration.

Marilyse Latour
Quality Assurance & Regulatory Affairs Manager
NEWDEAL SAS

Gaétane Vuaille
Director QA & RA European Operations
Integra LifeSciences

Copy: - Competent authority
In attached file: - Inspection instruction.

FIELD SAFETY NOTICE – INSPECTION PROCESS
Hintegra® total ankle prosthesis tibial and talar components
Legal manufacturer: **Newdeal SAS** - 97 allée Alexandre Borodine 69800 Saint Priest - France
March 2014
Involved batches: All non expired products.

APPENDIX A: List of references involved in the Field Safety Notice

HINTEGRA® Talar implants	301110	301111	301112	301113
	301114	301115	301116	301121
	301122	301123	301124	301125
	302110	302111	302112	302113
	302114	302115	302116	302121
	302122	302123	302124	302125

HINTEGRA® Tibial implants	301200	301201	301202	301203
	301204	301205	301206	301222
	301223	301224	301225	301232
	301233	301234	301235	302200
	302201	302202	302203	302204
	302205	302206	302222	302223
	302224	302225	302232	302233
	302234	302235		

HINTEGRA® Sensitive Talar implants	351152	351153	351154	351155
	351156	351512	351513	351514
	351515	352152	352153	352154
	352155	352156	352512	352513
	352514	352515		

HINTEGRA® Sensitive Tibial implants	351251	351252	351253	351254
	351255	351256	351522	351523
	351524	351525	351532	351533
	351534	351535	352251	352252
	352253	352254	352255	352256
	352522	352523	352524	352525
	352532	352533	352534	352535

FIELD SAFETY NOTICE ACKNOWLEDGMENT AND RETURN FORM
Hintegra® total ankle prosthesis tibial and talar components
Legal manufacturer: **Newdeal SAS** - 97 allée Alexandre Borodine 69800 Saint Priest - France
March 2014
Involved batches: All non expired products.

Please return the form back to :

Newdeal SAS,
Immeuble Séquoïa 2 -97, allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint-Priest - France
Attention to: Regulatory Affairs department
Or
By fax to: +33 (0)4 37 47 51 52
By email: newdeal.quality@integralife.com

With this form, I confirm that:

I have received, read and understood the information provided in the Newdeal Field Safety Notice notification regarding Hintegra® total ankle prosthesis tibial and talar components.

I have transferred this form together with the explicative letter to the relevant users. I will ensure that a duly Integra trained Representative will attend for each Hintegra® Prosthesis surgery in order to perform the inspection according to the instruction inspection before each Hintegra® surgery potentially using one of the products listed in Appendix A .

Distributor Name

Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Signature