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

INTEGRA
LIMIT UNCERTAINTY

Distributor

Saint-Priest, March XXth 2014

Object: **FIELD SAFETY NOTICE – VOLUNTARY RECALL**

Medical devices:	Surfix® Screw diameter 3.5mm length 22mm - ref. 285322S – Sterile Surfix® Screw diameter 3.5mm length 30mm - ref. 285330S – Sterile
Legal Manufacturer:	NEWDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest – **France**

Batch involved: ref. 285322S: **F6S6**.
Batch involved: ref. 285330S: **F6ZL**.

Madam, Sir,

Newdeal SAS, a company within Integra LifeSciences Group, has recently identified that certain screws of Surfix® screw diameter 3.5mm **length 22mm** (Catalog number 285322S – batch F6S6) have been packaged and labeled with the specifications of Surfix® screw diameter 3.5mm **length 30mm** (Catalog number 285330S – batch F6ZL). The batch number and screw length etched on the products are correct.

Although the risk of an adverse patient consequence has been determined to be not likely based onto health hazard evaluation, Newdeal SAS has made the decision to conduct a voluntary recall of the products.

We are notifying you of the recall as our records indicate that you have been supplied with Surfix® Screws ref. 285322S batch F6S6 and/or Surfix® Screws ref. 285330S batch F6ZL.

These devices may have been shipped either individually or with the following instrumentation set:

- UNI-CP™ compression plate
- Tibiaxys® Osteotomy and Arthrodesis System
- ADVANSYS® Dorsal Lisfranc Plate (DLP)
- ADVANSYS® Medial Lapidus Plate (MLP).

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 concerned devices, including those you had already sent to your customers, will be sent back to Integra for exchange. And you confirm that this recall notification has been circulated to all affected users / customers.

We will contact you upon receipt of this information to organize the return and exchange of the concerned products (Return Merchandize Authorization number and return instructions). Newdeal SAS will bear the costs of the products exchanged and related transport. **Thank you in advance to put this RMA number on the shipment to the attention of Sébastien Maître –Newdeal Quality Department.**

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.

Marilyse Latour
NEWDEAL SAS
Quality Assurance & regulatory Affairs Manager
In attached file: - Recall acknowledgment and Return Form

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RECALL ACKNOWLEDGMENT AND RETURN FORM

Surfix® screw diameter 3.5mm, Length 22mm sterile – Ref. 285322S
Surfix® screw diameter 3.5mm Length 30mm sterile – Ref. 285330S

Legal manufacturer: **Newdeal SAS -** 97 allée Alexandre Borodine 69800 Saint Priest - France
March 2014
Involved batches reference 285322S: **F6S6**
Involved batches reference 285330S: **F6ZL**

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: marilyse.latour@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 Surfix® screw diameter 3.5mm length 22mm and length 30mm.

I have transferred this form together with the explicative letter to the persons who have received the product. 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 to be exchanged.
Please indicate quantity in the table below.

☐ **No**, I do not have the affected product with affected references in my inventory or my final customers' inventory

Reference	Affected Lot Number	Quantity
285 322S	F6S6	
285 330S	F6ZL	

Distributor Name Contact Name

Street Address

City, Country, Postal Code Telephone

Email Signature