INTEGRA
LIMIT UNCERTAINTY

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

Saint Priest, January 18th 2017

Sujet: **URGENT – FIELD SAFETY NOTICE – RECALL NOTIFICATION LETTER**
Medical device:
UNI-CP™ - 2 holes compression plate interaxis 30mm
Référence :
330230S
Legal Manufacturer :
NEWDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest – France.
Batch involved:
FEDT

Madam, Sir,

Newdeal SAS, a company within Integra LifeSciences Group, has recently identified that UNI-CP™ plates, reference 330230S; batch FEDT, had a picture on their external label which did not correspond to this reference. Indeed, the picture corresponds to the U-shape plate with 4 holes while the reference and description of the product specify a plate with 2 holes.

However, only the picture of the product is incorrect. The description, reference, batch number indicated on the label and the plate inside the box conform to Newdeal's specifications.

While no injury or other adverse patient consequence was reported, Newdeal SAS has made the decision to conduct a voluntary recall of the batch FEDT.

We are notifying you of the recall as our records indicate that you have been supplied with some compression plates 2 holes reference: 330230S batches FEDT.

Description	Reference	Batch number
2 holes compression plate interaxis 30mm	330230S	FEDT

We kindly ask you to examine your inventory to determine if you have UNI-CP™ - 2 holes compression plate interaxis 30mm (batch FEDT), 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 UNI-CP™ - 2 holes compression plate interaxis 30mm (batch FEDT) 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
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

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 (1 page)

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

INTEGRA
LIMIT UNCERTAINTY

RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical device:
UNI-CP™ - 2 holes compression plate interaxis 30mm
Référence :
330230S
Legal Manufacturer :
NEWDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest – France.
Batch involved:
FEDT

January 2017

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 UNI-CP™ - 2 holes compression plate interaxis 30mm (batch FEDT).

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:

Description of affected product	References	Lot Number	Quantity
UNI-CP™ - 2 holes compression plate interaxis 30mm	330230S	FEDT	

☐ **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

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