

May XXth 2012

Customer address.

Subject: **FIELD SAFETY NOTICE - RECALL LETTER**
 Medical device: **Drilling guide for diameter 3.5 mm screw**
 Reference: **219 635**
 Legal manufacturer: **Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint Priest – France.**
 Batches involved: **E1DT-E4EX-E57T-E5YA-E64W-E6GN-E6RB-E6WP-E7UL-E86B-E8UC-E9PX-E9Q5-E9QD-EBNY-EEYJ-EF11-EFCM-EGT6-EH6X-EHL2-EJB3-EJZE-EKJ4-EKN4-EKZV-EKZW-EL3G-EL3X-ELH8-EMCQ-EMCX-EN19-ENR9-ENRA-ENS0-EPTL.**

Madam, Sir,

Newdeal SAS has become aware of incidents regarding the breakage of some **drilling guides for diameter 3.5 mm screw (reference : 219 635).**

The drilling guides for diameter 3.5mm screw (reference 219 635) are instruments included in the following Newdeal instrumentation sets:

- **TIBIAXYS® Ankle Arthrodesis Plating System**
- **TIBIAXYS® Distal Tibia and Fibula Osteotomy Plating Systems**
- **ADVANSYS® Dorsal Lisfranc Plate / ADVANSYS® Medial Lisfranc Plate**
- **Uni-CP™ Compression plating system**

Although most of the incidents occurred during Tibiaxys® surgeries, as a preventive measure, Newdeal SAS has made a decision to conduct a recall of the drilling guides included in the 4 above listed instrumentation sets.

Since March 2011, Newdeal has marketed a new version of the drilling guide, the reference remaining the same (219 635). Only « the old version » of the drilling guide is concerned by this recall.

In order to help you to identify the affected device (old version) please refer to the enclosed *Appendix - instruction sheet*.

We are notifying you of the recall as our records indicate that you have been supplied with some of these drilling guides.

Those ones may have been shipped either in an instrumentation set or individually packed.

Product	Reference	Batch	Quantity	Sent on
Drilling guide for diameter 3.5 mm screw (ref. 219 635)	219 635	XXXX	xx	dd/mm/YYYY

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.

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

With this form, you will ensure that all the devices, will be replaced by the new version of drilling guide (ref. 219 635).

We will contact you upon receipt of this information to organize the return of the concerned products.

Newdeal SAS will bear the costs of the products exchanged and related transport. We would appreciate if you could send back the devices to be exchanged by TNT Global Express shipment. The Newdeal SAS account number to be given to TNT is: 78739.

A RMA number will be assign to you as soon as the form will be returned, thanking you in advance to put this number on the shipment to the attention of Sébastien Maître -Newdeal Quality Department.

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**

Copy: - Competent authority

In attached file: - Recall acknowledgment and Return Form
-Instruction sheet.

RECALL ACKNOWLEDGMENT AND RETURN FORM
Drilling guide for diameter 3.5 mm screw
Reference: 219 635
Legal manufacturer: **Newdeal SAS** - 97 allée Alexandre Borodine 69800 Saint Priest - France
May 2012
Involved batches: **E1DT-E4EX-E57T-E5YA-E64W-E6GN-E6RB-E6WP-E7UL-E86B-E8UC-E9PX-E9Q5-E9QD-EBNY-EEYJ-EF11-EFCM-EGT6-EH6X-EHL2-EJB3-EJZE-EKJ4-EKN4-EKZV-EKZW-EL3G-EL3X-ELH8-EMCQ-EMCX-EN19-ENR9-ENRA-ENS0-EPTL.**

Customer Address.

Among the drilling guide for diameter 3.5 mm screw (ref. 219 635), old version, that we have received,
 will be sent back for exchange by a “new version” of the drilling guide for diameter 3.5 mm screw (ref. 219 635).

With this form, I confirm that all the drilling guides (ref. 219 635), old version, have been isolated and will be sent back to be exchanged.
I attest I have received this letter; together with the explicative letter and the instruction sheet.
I ensure that the form is duly returned and signed.

Thanks to complete and send back quickly

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

Name: _____ FONCTION: _____
Signature: _____
Date: _____

INSPECTION SHEET
 Identification of the old version of **drilling guide for diameter 3.5 mm screw** -
 Reference: **219 635**
 To be removed and shipped back to NEWDEAL S.A.S.
ONLY THE OLD VERSION IS TO BE RETURNED.

The drilling guide for diameter 3.5mm screw (reference 219 635) are instruments included in the following Newdeal instrumentation sets:

- **TIBIAXYS® Ankle Arthrodesis Plating System**
- **TIBIAXYS® Distal Tibia and Fibula Osteotomy Plating Systems**
- **ADVANSYS® Dorsal Lisfranc Plate /ADVANSYS® Medial Lisfranc Plate**
- **Uni-CP™ Compression plating system**

Inspection procedure:

STEP 1: -Identify the drilling guides (reference 219 635) included in the instruments sets or individually packed.

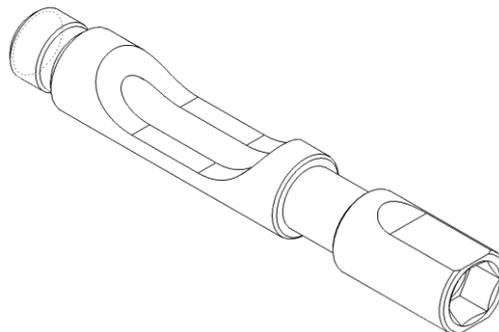
STEP 2: - Assess the device’s version (old or new version) as indicated by the pictures below:

Associated lots numbers:

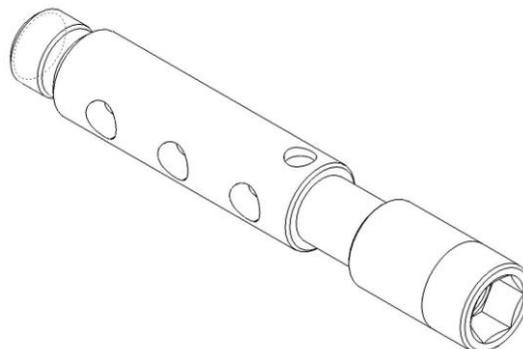
**E1DT / E4EX / E57T /
 E5YA / E64W / E6GN
 / E6RB / E6WP / E7UL
 / E86B / E8UC / E9PX
 / E9Q5 / E9QD /
 EBNY / EEYJ / EF11 /
 EFCM / EGT6 / EH6X
 / EHL2 / EJB3 / EJZE
 / EKJ4 / EKN4 / EKZV
 / EKZW / EL3G / EL3X
 / ELH8 / EMCQ /
 EMCX / EN19 / ENR9
 / ENRA / ENS0 /
 EPTL.**

**EPTQ / EPTQ/1 /
 EQD7 / EQDD /
 F1L7 / F1L8 / F2ZA
 / F2ZB / F37N and
 future lots.**

OLD VERSION



NEW VERSION



STEP 3: -If the old version is identified: please complete the “Recall acknowledgment and Return Form” and follow the instructions for product return:
 -If the new version is identified: keep the device.