INTEGRA
LIMIT UNCERTAINTY

To the attention of Medical Device Vigilance responsible / Central Pharmacy

INTEGRA
LIMIT UNCERTAINTY

Saint Priest, 14/10/16

Subject: **URGENT - FIELD SAFETY NOTICE - RECALL NOTIFICATION LETTER**

Medical devices:
Drill dia. 1.9mm
References:
119618
Legal manufacturer:
Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.
Concerned batches:
FHBY and FE58

Dear Valued Customer,

Newdeal SAS, a company within Integra LifeSciences Group, has recently identified that two batches of Drills dia. 1.9mm (reference 119618 – batches FHBY and FE58) are not enough sharp to prepare the screws holes.

Consequently, given that only one drill reference 119618 is available in the Newdeal instrumentation kits, the defect of the drill can involve an increase of the surgery time of around 10 minutes and require a higher pressure on the drill. This pressure may cause minimal transient tissue damage and difficulties to achieve the surgery.
Although this defect is easily recognized during the use, an increase of surgery time will be needed in order to find a similar drill in the operating room.
However, the risk of adverse health consequences has been defined as negligible according to our evaluation.

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

We are notifying you of the recall as our records indicate that you have been supplied with some **drills dia. 1.9mm reference: 119618 batches FHBY and/or FE58.**

Description of affected product	References	Affected Lot Number
Drill dia. 1.9mm	119618	FHBY; FE58

We kindly ask you to examine your inventory to determine if you have drill dia. 1.9mm reference: 119618 batches FHBY and/or FE58, please quarantine them.

Once the audit of your 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.

FSN-HHE-133-031016

Integra LifeSciences Services (France)
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 59 00 office ▪ 33 (0)4 37 47 59 99 fax ▪ integralife.com
Société par Actions Simplifiée au capital de 37.000 € ▪ NAF 4646Z ▪ 492 534 466 RCS Lyon
Deutsche Bank AG Paris FR76 1778 9000 0110 5107 2400 081 DEUTFRPP ▪ No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466

With this form, you will ensure that all the devices drill dia. 1.9mm reference: 119618 batches FHBY and/or FE58 affected, will be sent back. You also confirm that this notification has been forwarded to every concerned user.

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 Integra 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,

Angélique Aubert
Compliance coordinator
Europe, Middle-East & Africa

Enclosed: Recall Acknowledgment and Return Form (1 page)

Integra LifeSciences Services (France)
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 59 00 office ▪ 33 (0)4 37 47 59 99 fax ▪ integralife.com
Société par Actions Simplifiée au capital de 37.000 € ▪ NAF 4646Z ▪ 492 534 466 RCS Lyon
Deutsche Bank AG Paris FR76 1778 9000 0110 5107 2400 081 DEUTFRPP ▪ No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466

INTEGRA
LIMIT UNCERTAINTY

RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical devices:
Drill dia. 1.9mm
References:
119618
Legal manufacturer:
Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.
Concerned batches:
FHBY and FE58

October 2016

Please send the form back to :

By fax/telecopy: +33 (0)4 37 47 59 30
Or by e-mail: *emea-fsca-recon@integralife.com*
With this form, I confirm that:

I have received, read and understood the information provided in the Integra Recall notification regarding drills dia. 1.9mm reference: 119618 batches FHBY and/or FE58.

My inventory has been reviewed and the results are as follow (*please tick the appropriate answer*):

☐ **Yes**, I do have affected product(s) in my 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
Drill dia. 1.9mm	119618		

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

I ensure that all the affected products 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

Integra LifeSciences Services (France)
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 59 00 office ▪ 33 (0)4 37 47 59 99 fax ▪ integralife.com
Société par Actions Simplifiée au capital de 37.000 € ▪ NAF 4646Z ▪ 492 534 466 RCS Lyon
Deutsche Bank AG Paris FR76 1778 9000 0110 5107 2400 081 DEUTFRPP ▪ No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466