INTEGRA
LIMIT UNCERTAINTY

To the attention of Medical Device Vigilance responsible / Central Pharmacy

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LIMIT UNCERTAINTY

Saint Priest, 08/02/2016

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

Medical devices:
AO "2 in 1" cannulated drill dia. 2.2/3.0mm L.32mm - STERILE
Reference: 159023S
Legal manufacturer:
Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.
Concerned batches:
FBYD

Dear Valued Customer,

Newdeal SAS, a company within Integra LifeSciences Group, has recently identified that one batch of AO "2 in 1" cannulated drills dia. 2.2/3.0mm L.32mm sterile (Catalog number 159023S – batch FBYD) has been packaged and labeled with the specifications (designation and reference) of "2 in 1" cannulated drill dia. 2.2/3.0mm L.12mm (Catalog number 119027S – batch FBYD). This label error is only located on the inner label, the outer label of the product is correct.

While no injury or other adverse patient consequence was reported, Newdeal SAS has made a 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 AO "2 in 1" cannulated drill dia. 2.2/3.0mm L.32mm sterile (Catalog number 159023S – batch FBYD).

Description of affected product	Reference	Affected Lot Number
AO "2 in 1" cannulated drill dia. 2.2/3.0mm L.32mm - STERILE	159023S	FBYD

We kindly ask you to examine your inventory to determine if you have AO "2 in 1" cannulated drill dia. 2.2/3.0mm L.32mm – STERILE, lot number FBYD If so, 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.

With this form, you will ensure that all the devices AO "2 in 1" cannulated drill dia. 2.2/3.0mm L.32mm – STERILE, lot number FBYD 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 and exchange 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

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

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)

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RECALL ACKNOWLEDGMENT AND RETURN FORM

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Reference: 159023S
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Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.
Concerned batches:
FBYD

February 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 notification regarding AO "2 in 1" cannulated drills dia. 2.2/3.0mm L.32mm sterile (Catalog number 159023S – batch FBYD).
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 to be exchanged.

Please indicate quantity in the table below:

Description of affected product	Reference	Affected Lot Number	Quantity
AO "2 in 1" cannulated drill dia. 2.2/3.0mm L.32mm - STERILE	159023S	FBYD	

☐ **No**, I do not have the affected product with affected Lot Number 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

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