INTEGRA
LIMIT UNCERTAINTY

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

INTEGRA

Saint Priest, 06/03/17

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

Medical devices:
PANTA® and PANTA® XL nails
Reference: 500050 - 500080 - 500150 - 500180 - 500250 - 500280 - 500350 - 500380 - 510111 - 510141 - 510211 - 510241 - 510311 - 510341
Legal manufacturer:
Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.
Concerned batches:
All non-expired and unused products – Listed below

Dear Valued Customer,

Newdeal SAS, a company of Integra LifeSciences, has identified, through an internal evaluation, the possibility of sealing defect for the Panta® or Panta® XL packaging. The defect is a non-homogeneous seal and if it were not completely sealed, the sterility of the packaging or the nail itself could be compromised.

Loss of sterility may result in a wound infection that is significant but reversible, requiring intervention beyond standard-of-care. The package defect might not be easily detectable upon visual inspection prior to use but an adverse health consequence is unlikely to occur based on our health hazard evaluation.

The review of the available clinical data on the Panta® or Panta® XL nails does not raise an abnormal infection rate, consequently no specific follow up for patient implanted is required.

While no adverse event or patient injury has been reported due any package defect, Newdeal SAS has made the decision to conduct a voluntary recall of any unused and unexpired products listed below.

We are notifying you of this recall as our records indicate that you have been supplied with **Panta® or Panta® XL nails listed below.**

Description of affected product	Reference	Affected Lot Number
Panta® nails	500050	F33A; F33B; F3BN; F3Y5; F3Y6; F4S4; F56Y; F5LZ; F64W; F7C8; F7C9; F8SZ; F9PC; FCUG; FCUH; FEDW; FEVR; FGAX; FGLN; FHLP
	500080	F0F1; F64X; F81Y; F81Z; FEVS; FGLP; FGSK
	500150	F15L; F15L/1; F1ZQ; F27U; F27V; F3Y7; F5M0; F60W; F64Y; F64Z; F6L3; F7CA; F7CB; F7CC; F7CD; F821; F822; F8T1; F8T2; F9D6; F9D7; FEDX; FFB9; FG4T; FGSL; FHLR

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

Description of affected product	Reference	Affected Lot Number
Panta® nails	500180	F1ZS; F33C; F3M9; F4H4; F4ZZ; F68B; F823; F824; F8T3; FDEC; FEDY; FFBA; FFQL
	500250	EP14; F0WQ; F15M; F4H5; F500; F5M1; F650 ; F825; F826; F827; F828; F8T4; FGLQ; FGSM
	500280	F27T; F33D; F3BP; F3MA; F4H6; F5M2; F6L4; F829; F82A; F82B; F82C; F8T5; FFBB
	500350	E2W1/1; F3BQ; F3MB; F3MD; F3Y8; F4H7; F5M3; F651; F6TT; FF3B
	500380	F3BR; F3MC; F4S5; F5M4; F60X; F652; F82D; F82E; F8T6; FAF2
Panta® XL nails	510111	F3H8; F4XA; F507; F5M5; F68C; F82F; F82G; F8T7; F9DC; F9DD
	510141	ELSS; EPFZ; F3H9; F82H; F82J; F8LG; FEVT; FFBC
	510211	F6JA; F82K; F82L; F8C8; F8T8; FFQN; FG4V
	510241	F5M6; F82M; F82N; F8C9; F8T9
	510311	EPG0/1; EPG0/2; EPG0/3; EPG0/4; EPG0/5; F82P; F82Q; F8TA
	510341	F4H8; F508; F657; F8TB

We kindly ask you to examine your inventory to determine if you have Panta® or Panta® XL nails listed above, 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 Panta® or Panta® XL nails 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.

Integra Customer Service will contact you upon receipt of this information to organize the return of the concerned products (Return Merchandise Authorization number assignment).

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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,

[redacted]

Enclosed: Recall Acknowledgment and Return Form (1 page)

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RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical devices:

PANTA® and PANTA® XL nails

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Legal manufacturer:

Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.

Concerned batches:

All non-expired and unused products listed in the table above

March 2017

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 PANTA® and PANTA® XL nails.

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.

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.

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 and lot numbers in the table below:

Description of affected product	Reference	Affected Lot Number	Quantity
Panta® or Panta® XL nails			

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

Distributor / Healthcare facility name

Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Signature

FSN-HHE-136-140217

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