

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

Saint Priest, February 24th 2017

Sujet: **URGENT – FIELD SAFETY NOTICE – RECALL NOTIFICATION LETTER**

Medical device:

PANTA® and PANTA® XL nails

Reference:

**500050 - 500080 - 500150 - 500180 - 500250 - 500280 - 500350 - 500380 - 510111 - 510141 -
510211 - 510241 - 510311 - 510341**

Legal Manufacturer :

*NEWDEAL SAS, Immeuble Séquoia 2 - 97 allée Alexandre Borodine -
Parc Technologique de la Porte des Alpes - 69800 Saint Priest – France.*

Batch involved:

All non-expired and unused products listed on Appendix 1

Madam, Sir,

Newdeal SAS, a company within Integra LifeSciences Group, has recently 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 on appendix 1.

We are notifying you of the recall as our records indicate that you have been supplied with some Panta® or Panta® XL nails listed on appendix 1.

We kindly ask you to examine your inventory to determine if you have Panta® or Panta® XL nails listed on appendix 1, 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.

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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 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).

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 (2 pages)
Appendix 1 – List of references and batches involved (2 pages)

RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical device:

PANTA® and PANTA® XL nail

Référence :

500050 - 500080 - 500150 - 500180 - 500250 - 500280 - 500350 - 500380 - 510111 - 510141 - 510211 - 510241 - 510311 - 510341

Legal Manufacturer :

NEWDEAL SAS, Immeuble Séquoia 2 - 97 allée Alexandre Borodine - Parc Technologique de la Porte des Alpes - 69800 Saint Priest - France.

Batch involved:

**All non-expired and unused products listed on Appendix 1
February 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 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.

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:

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

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APPENDIX 1 – List of references and batches involved by the recall

Model #	Batch	Model #	Batch	Model #	Batch
500050	F33A	500150	F64Y	500250	F500
500050	F33B	500150	F64Z	500250	F5M1
500050	F3BN	500150	F6L3	500250	F650
500050	F3Y5	500150	F7CA	500250	F825
500050	F3Y6	500150	F7CB	500250	F826
500050	F4S4	500150	F7CC	500250	F827
500050	F56Y	500150	F7CD	500250	F828
500050	F5LZ	500150	F821	500250	F8T4
500050	F64W	500150	F822	500250	FGLQ
500050	F7C8	500150	F8T1	500250	FGSM
500050	F7C9	500150	F8T2	500280	F27T
500050	F8SZ	500150	F9D6	500280	F33D
500050	F9PC	500150	F9D7	500280	F3BP
500050	FCUG	500150	FEDX	500280	F3MA
500050	FCUH	500150	FFB9	500280	F4H6
500050	FEDW	500150	FG4T	500280	F5M2
500050	FEVR	500150	FGSL	500280	F6L4
500050	FGAX	500150	FHLR	500280	F829
500050	FGLN	500180	F1ZS	500280	F82A
500050	FHLP	500180	F33C	500280	F82B
500080	F0F1	500180	F3M9	500280	F82C
500080	F64X	500180	F4H4	500280	F8T5
500080	F81Y	500180	F4ZZ	500280	FFBB
500080	F81Z	500180	F68B	500350	E2W1/1
500080	FEVS	500180	F823	500350	F3BQ
500080	FGLP	500180	F824	500350	F3MB
500080	FGSK	500180	F8T3	500350	F3MD
500150	F15L	500180	FDEC	500350	F3Y8
500150	F15L/1	500180	FEDY	500350	F4H7
500150	F1ZQ	500180	FFBA	500350	F5M3
500150	F27U	500180	FFQL	500350	F651
500150	F27V	500250	EP14	500350	F6TT
500150	F3Y7	500250	F0WQ	500350	FF3B
500150	F5M0	500250	F15M	500380	F3BR
500150	F60W	500250	F4H5	500380	F3MC

Model #	Batch
500380	F4S5
500380	F5M4
500380	F60X
500380	F652
500380	F82D
500380	F82E
500380	F8T6
500380	FAF2
510111	F3H8
510111	F4XA
510111	F507
510111	F5M5
510111	F68C
510111	F82F
510111	F82G
510111	F8T7
510111	F9DC
510111	F9DD

Model #	Batch
510141	ELSS
510141	EPFZ
510141	F3H9
510141	F82H
510141	F82J
510141	F8LG
510141	FEVT
510141	FFBC
510211	F6JA
510211	F82K
510211	F82L
510211	F8C8
510211	F8T8
510211	FFQN
510211	FG4V
510241	F5M6
510241	F82M
510241	F82N

Model #	Batch
510241	F8C9
510241	F8T9
510311	EPG0/1
510311	EPG0/2
510311	EPG0/3
510311	EPG0/4
510311	EPG0/5
510311	F82P
510311	F82Q
510311	F8TA
510341	F4H8
510341	F508
510341	F657
510341	F8TB