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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 Séquoïa 2 - 97 allée Alexandre Borodine - Pare 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 tor 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.

Newdeal
Siège Social: Immeuble Séquoia 2 • 97 allée Alexandre Borodine • Pare 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**
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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 wil! 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 teel free to contact me for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

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In attached file: Recall acknowledgment and Return Form (2 pages)
Appendix 1 - List of references and batches involved (2 pages)

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INTEGRA'I
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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 :

NE.WDEAL SAS, Immeuble Séquoïa 2 - 97 allée Alexandre Borodine - Pare 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, 1 confirm that:

1 have received, read and understood the information provided in the Integra Recall notification regarding PANTA® and PANTA® XL nails.

1 have transferred this recall letter to the persons to whom I have sold and/or place on consignment the concerned products. 1 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):*

D **Yes, 1** 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:

D **No, 1** do not have the affected product in my inventory.

1 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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RECALL ACKNOWLEDGMENT AND RETURN FORM

Medica! 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, lmmeub/e Séquoïa 2 - 97 al/ée Alexandre Borodine - Pare Techno/ogique de la Porte des Alpes - 69800 Saint Priest- France.

Batch involved:

All non-expired and unused products listed on Appendix 1

February 2017

Reference	Affected batch	Quantity

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

Model#	Batch
500050	F33A
500050	F33B
500050	F3BN
500050	F3Y5
500050	F3Y6
500050	F4S4
500050	F56Y
500050	F5LZ
500050	F64W
500050	F7C8
500050	F7C9
500050	F8SZ
500050	F9PC
500050	FCUG
500050	FCUH
500050	FEDW
500050	FEVR
500050	FGAX
500050	FGLN
500050	FHLP
500080	FOFl
500080	F64X
500080	F81Y
500080	F81Z
500080	FEVS
500080	FGLP
500080	FGSK
500150	F15L
500150	F15L/1
500150	FlZQ
500150	F27U
500150	F27V
500150	F3Y7
500150	F5MO
500150	F60W

Model#	Batch
500150	F64Y
500150	F64Z
500150	F6L3
500150	F7CA
500150	F7CB
500150	F7CC
500150	F7CD
500150	F821
500150	F822
500150	F8T1
500150	F8T2
500150	F9D6
500150	F9D7
500150	FEDX
500150	FFB9
500150	FG4T
500150	FGSL
500150	FHLR
500180	FlZS
500180	F33C
500180	F3M9
500180	F4H4
500180	F4ZZ
500180	F68B
500180	F823
500180	F824
500180	F8T3
500180	FDEC
500180	FEDY
500180	FFBA
500180	FFQL
500250	EP14
500250	FOWQ
500250	F15M
500250	F4H5

Model#	Batch
500250	F500
500250	F5M1
500250	F650
500250	F825
500250	F826
500250	F827
500250	F828
500250	F8T4
500250	FGLQ
500250	FGSM
500280	F27T
500280	F33D
500280	F3BP
500280	F3MA
500280	F4H6
500280	F5M2
500280	F6L4
500280	F829
500280	F82A
500280	F82B
500280	F82C
500280	F8T5
500280	FFBB
500350	E2W1/1
500350	F3BQ
500350	F3MB
500350	F3MD
500350	F3Y8
500350	F4H7
500350	F5M3
500350	F651
500350	F6TI
500350	FF3B
500380	F3BR
500380	F3MC

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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

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