INTEGRA
LIMIT UNCERTAINTY

To the attention of Medical Device Vigilance responsible / Central Pharmacy

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Saint Priest, 23/06/16

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

Medical devices:
ACHILLON® Minimally invasive Achilles tendon suture system
Reference: 119700
Legal manufacturer:
Newdeal SAS - 97 allée Alexandre Borodine 69800 Saint-Priest – France.
Concerned batches:
All non-expired products

Dear Valued Customer,

Newdeal SAS, a company of Integra LifeSciences, has identified, through an internal evaluation, there is a possibility that one section of the secondary package (outer blister) Tyvek seal for the Achillon® Suture System may not remain completely sealed.

The section of the seal affected is adjacent to the finger-lift used to open the outer blister and if it were not completely sealed, the sterility assurance of the exterior surface of the inner package may be compromised.

If packaging is compromised, device sterility may be lost. 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 Newdeal internal evaluation additionally determined the Achillon® devices inside the packages were sterile.

The review of the available clinical data on the Achillon® Suture System 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 with reference 119700.

We are notifying you of this recall as our records indicate that you have been supplied with **Achillon® Suture System.**

Description of affected product	Reference	Affected Lot Number
ACHILLON® Minimally invasive Achilles tendon suture system	119700	All non-expired lots

FSN-HHE-129-060616

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

We kindly ask you to examine your inventory to determine if you have ACHILLON® Suture System ref. 119700, 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 ACHILLON® Suture System ref. 119700 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)

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RECALL ACKNOWLEDGMENT AND RETURN FORM

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June 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 ACHILLON® Minimally invasive Achilles tendon suture system, reference 119700.

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 and lot numbers in the table below:

Description of affected product	Reference	Lot Number	Quantity
ACHILLON® Minimally invasive Achilles tendon suture system	119700		

☐ **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

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