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

Distributor Integra

Saint-Priest, June 14th 2016

Object: **URGENT - FIELD SAFETY NOTICE - VOLUNTARY MEDICAL DEVICES RECALL**

Medical device: ACHILLON® Minimally invasive Achilles tendon suture system
Reference: 119700

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

Concerned batches: All non-expired and unused products.

Madam, Sir,

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.

An 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.

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.

We will contact you upon receipt of this information to organize the return of the concerned products. Newdeal SAS will bear the costs related to products transport.

Thanking you in advance to assign a RMA number and inform the involved customer to put this number on the shipment to the attention of Sébastien Maître -Newdeal Quality Department.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

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

Your cooperation is appreciated, and we thank you for your continued collaboration.

Marilyse LATOUR
Quality Assurance & Regulatory Affairs Manager
NEWDEAL SAS

Enclosed: recall acknowledgment and return form

RECALL ACKNOWLEDGMENT AND RETURN FORM
Achillon® Minimally invasive Achilles tendon suture system
Reference: 119700
Legal manufacturer: **Newdeal SAS** - 97 allée Alexandre Borodine 69800 Saint Priest - France
June 2016
Involved batches: All non-expired and unused products.

Please return the form back to:

Newdeal SAS,
Immeuble Séquoïa 2 -97, allée Alexandre Borodine
Parc Technologique de la Porte des Alpes
69800 Saint-Priest - France
Attention to: Regulatory Affairs department
Or
By fax to: +33 (0)4 37 47 51 52
By email: newdeal.quality@integralife.com

With this form, I confirm that:

I have received, read and understood the information provided in the Newdeal Field Safety Notice notification regarding Achillon® Suture System.

I have transferred this form together with the explicative letter to the persons who have received the product with reference 119700. 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 in the table below.

☐ **No**, I do not have the affected product with affected references in my inventory or my final customers' inventory

Distributor Name Contact Name

Street Address

City, Country, Postal Code Telephone

Email Signature

RECALL ACKNOWLEDGMENT AND RETURN FORM
Achillon® Minimally invasive Achilles tendon suture system
Reference: 119700
Legal manufacturer: **Newdeal SAS** - 97 allée Alexandre Borodine 69800 Saint Priest - France
June 2016
Involved batches: All non-expired and unused products.

Reference	Affected Lot Number	Quantity

Distributor Name: _____ Name and function: _____

Signature: _____ Date: _____