



رقم المحفوظات: ٧/٢٥
رقم الصادر: ١٤٨/٢٧٧٤
بيروت، في: ٢ - أيار - ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Joint prosthesis, shoulder. PyroTITAN humeral resurfacing arthroplasty (CHRA)

الجهاز المعنى بالمتابعة:

- Joint prosthesis, shoulder. PyroTITAN humeral resurfacing arthroplasty (CHRA)
- Trade Mark: Integra LifeSciences ORTHOPAEDIC
- Local Representative: Asmar Medical

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد أعلاه مما يستدعي إعادة العملية الجراحية، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يلف:

دائرة البرامج والمشاريع ✓

- المستشفيات الحكومية

- المحفوظات

مدير عام الصحة

د. وليد عمار



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

July 8th, 2013

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

Medical device: **PyroTITAN™ Humeral Resurfacing Arthroplasty (CHRA)**

Reference: **See table below**

Batches involved: **All batches**

Legal manufacturer:

ASCENSION ORTHOPEDICS, INC. - 8700 Cameron Road - Austin, Texas 78754 - USA

<Distributor Name>

Dear Distributor,

Integra LifeSciences is conducting a voluntary recall of ALL lots of the PyroTITAN™ Humeral Resurfacing Arthroplasty (CHRA) (hereafter the "Product") due to infrequent complaint reports of implant fractures that were observed post-operatively and required revision surgeries. The Products being recalled are listed below.

Product Code	Description	Product Code	Description
CHRA-910-38/14-WW	PyroTitan Size 38-14	CHRA-910-47/20-WW	PyroTitan Size 47-20
CHRA-910-41/15-WW	PyroTitan Size 41-15	CHRA-910-50/18-WW	PyroTitan Size 50-18
CHRA-910-41/18-WW	PyroTitan Size 41-18	CHRA-910-50/21-WW	PyroTitan Size 50-21
CHRA-910-44/16-WW	PyroTitan Size 44-16	CHRA-910-53/19-WW	PyroTitan Size 53-19
CHRA-910-44/19-WW	PyroTitan Size 44-19	CHRA-910-53/22-WW	PyroTitan Size 53-22
CHRA-910-47/17-WW	PyroTitan Size 47-17	CHRA-910-56/21-WW	PyroTitan Size 56-21

The national competent authority of your country has been informed of this recall.

Our records indicate you have received PyroTITAN™ Humeral Resurfacing Arthroplasty (CHRA) Product and / or distributed them to surgeons. To this end, we ask you to do the following:

1. **STOP distributing the Product immediately.**
2. Identify any surgeon clients you have already shipped PyroTITAN Humeral Resurfacing Arthroplasty (CHRA) to and send them a copy of the attached Surgeon's Letter.
3. **Complete the attached form, return it as indicated on the form and keep a copy for your records.**
 - a. Check the box that indicates you will comply with the above 2 instructions.
 - b. If you have any affected Product, check the box "Yes" to indicate you or your customers have product in inventory, and record the quantity of each of the products you have on the form.
 - c. If you do not have any product, check the box "No" to indicate you do not have the affected product.

CHRA Recall letter – Page 1 / 2

Integra LifeSciences Services (France)

Siège Social : Immeuble Séquoia 2 • 97 allée Alexandre Borodine • Parc Technologique de la Porte des Alpes •
69800 Saint Priest • France

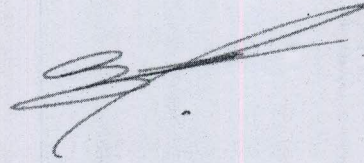
33 (0)4 37 47 59 00 office • 33 (0)4 37 47 59 99 fax • integralife.com

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

5. When the form is received, Integra LifeSciences will contact you with Product return instructions to credit your account as appropriate.

Thank you in advance for your timely attention to, and cooperation in, completing this recall.



Jean-Baptiste EBERST
Senior Regulatory Affairs Project Manager
Europe, Middle East, Africa
Extremity Reconstruction Division
+33 (0) 437 47 59 15
emea-fsca-recon@integralife.com

Attachments:

Distributor Recall Acknowledgment and Return Form
Surgeon's Letter

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