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.

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

The completed form ensures that you and Integra have achieved effectiveness in communicating this information that is required by regulatory authorities. Regulatory agencies may perform audits of your records of the field action to verify that appropriate field actions have been taken.

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
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Attachments:
Distributor Recall Acknowledgment and Return Form
Surgeon's Letter

DISTRIBUTOR RECALL ACKNOWLEDGMENT AND RETURN FORM

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

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

IMPORTANT: Return this form even if you have no product to return to:
By fax/telecopy to: +33 (0)4 37 47 59 30 **OR**
by e-mail (scan) to: emea-fsca-recon@integralife.com

Distributor: <Distributor Name>

☐ I have read the Recall Letter and I will:
1) …STOP distributing the affected Products.
2) …send a copy of the Surgeon's letter to surgeon clients I have already supplied CHRA product to.

☐ **"No":** I have reviewed my inventory of CHRA Product and **do not have any recalled Product** (including customers' inventory).

☐ **"Yes":** I have reviewed my inventory of CHRA Product and **have affected Product and quantities** as recorded below (including customers' inventory).

Product Code	Description	Have in My Inventory?	If "Yes", Quantity
CHRA-910-38/14-WW	PyroTitan Size 38-14	☐ **Yes**	
CHRA-910-41/15-WW	PyroTitan Size 41-15	☐ **Yes**	
CHRA-910-41/18-WW	PyroTitan Size 41-18	☐ **Yes**	
CHRA-910-44/16-WW	PyroTitan Size 44-16	☐ **Yes**	
CHRA-910-44/19-WW	PyroTitan Size 44-19	☐ **Yes**	
CHRA-910-47/17-WW	PyroTitan Size 47-17	☐ **Yes**	
CHRA-910-47/20-WW	PyroTitan Size 47-20	☐ **Yes**	
CHRA-910-50/18-WW	PyroTitan Size 50-18	☐ **Yes**	
CHRA-910-50/21-WW	PyroTitan Size 50-21	☐ **Yes**	
CHRA-910-53/19-WW	PyroTitan Size 53-19	☐ **Yes**	
CHRA-910-53/22-WW	PyroTitan Size 53-22	☐ **Yes**	
CHRA-910-56/21-WW	PyroTitan Size 56-21	☐ **Yes**	

Name: _____ **Signature/Date:** _____
(Printed Name)

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July 8th, 2013

Subject: **FIELD SAFETY NOTICE – VOLUNTARY RECALL**

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

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

Dear Physician,

Integra LifeSciences is conducting a voluntary recall of ALL non-implanted sizes and lots of the PyroTITAN™ Humeral Resurfacing Arthroplasty (CHRA) device due to infrequent complaint reports of implant fractures that were observed post-operatively and required revision surgeries. Most confirmed cases of implant breakage have occurred as a result of excessive loading and within a year of being implanted. Excessive loads placed on the implant through high impact activities or sudden trauma can damage an artificial joint, particularly in the presence of poor bone stock. High impact activity may cause loosening or fracture of the implant. The breakage can result in glenohumeral joint pain and possible damage to the surrounding tissues.

The products that are 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

Your distributor will be contacting you regarding the return of any non-implanted product you may have.

In addition to recalling ALL non-implanted lots of the CHRA, Integra also recommends you consider the "Warning" below in the context of your normal practice and post-operative follow-up treatment of any patients having received this implant.

> "*With this implant, sudden breakage of the prosthesis resulting from excess loading is possible. Excessive loads placed on the implant through high impact activities or sudden trauma can damage the artificial joint, particularly in the presence of poor bone stock. High impact activity may cause loosening or fracture of the implant.*
>
> *Patient selection is critical to the success of the procedure. The patient's weight, occupation, and activity level should be considered when choosing to implant this prosthesis. Severe bone loss or poor prognosis for wound healing may present increased risks of failure.*

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Proper implant selection and placement of the prosthesis is critical. Incorrect positioning of the prosthesis may result in unusual loads and a subsequent reduction in service life of the implant."

Please feel free to contact Integra LifeSciences with any questions you might have regarding this field safety notice and supportive actions.
Sincerely,

Jason Kirsch
Sr. Product Manager
Extremity Reconstruction
Integra LifeSciences
Austin, TX 78754 USA
TEL: 001-(512) 836-5001