INTEGRA
LIMIT UNCERTAINTY

Saint Priest, 28/12/17

Subject: **URGENT - FIELD SAFETY NOTICE - NOTIFICATION LETTER**
Medical devices:
TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials

Reference:
TRL092002506; TRL092002507; TRL092002508; TRL092002509; TRL092002510; TRL092002511; TRL092002512; TRL092002513; TRL092002514; TRL092002515; TRL092002516

Legal manufacturer:
Ascension Orthopedics, Inc. – 8700 Cameron road, Suite 100, Austin Texas 78754 USA

Concerned lot:
Lots listed below

Dear Valued Customer,

Ascension Orthopedics Inc, a company within Integra LifeSciences Group, has received complaint reports related to stem trial breakage. The information provided to Integra for these fractures suggest that they all occurred during insertion/impaction or extraction of the humeral stem trial while preparing the humeral canal and/or trialing for the product.

The root cause concludes that breakage occurs when the surgical techniques (Titan™ reverse shoulder system n° 0368399-3, Titan™ modular shoulder system n°0370689-2) are not strictly followed with using a larger mallet than the slotted mallet (ref: MAL092008501) provided in the set.

It has been determined through review of current post market data that in less than 1% of the cases using the affected device may result in the trial becoming retained in the humerus. If the stem trial can be easily extracted, the short-term consequences include briefly extended surgical procedure time. If the stem broach cannot be easily extracted from the canal, a cortical slit or window may be required. The extension of the exposure may require changing from a press fit to a cemented long stem application. If either is required, the osteotomy will consolidate with no permanent health consequences.

Consequently, out of abundance of caution the legal manufacturer has decided to change the design of TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials to reduce the breakage risk. Those new revision will be available during the first quarter 2018.

You can continue to use the current version of TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials while following the surgical techniques (Titan™ reverse shoulder system n° 0368399-3, Titan™ modular shoulder system n°0370689-2).

We are notifying you as our records indicate that you have been supplied with some Integra TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials.

FSN-HHE-142-08122017

Integra LifeSciences Services (France) • Siège Social : Immeuble Séquoia 2 - 97 allée Alexandre Borodine
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No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466

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Description of affected product	Reference	Affected Lot Number
TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials	TRL092002506	19419-1; 15916-1; 15457-1; 201274-1 201893-1; 2046177
	TRL092002507	19419-2; 15916-2; 15457-2; 201274-2; 201893-2; 2046178
	TRL092002508	19419-3; 15916-3; 15457-3; 201274-3; 201893-3; 2046179
	TRL092002509	19419-4; 15916-4; 15457-4; 201274-4; 201893-4; 20461710
	TRL092002510	19419-5; 15916-5; 15457-5; 201274-5; 201893-5; 20461711
	TRL092002511	19419-6; 15916-6; 15457-6; 201274-6; 201893-6; 20461712
	TRL092002512	19419-7; 15916-7; 15457-7; 201274-7; 201893-7; 20461713
	TRL092002513	19419-8; 15916-8; 15457-8; 201274-8; 201893-8; 20461714
	TRL092002514	19419-9; 15916-9; 15457-9; 201274-9; 201893-9; 20461715
	TRL092002515	19419-10; 15916-10; 15457-10; 201274-10; 201893-10; 20461716
	TRL092002516	19419-11; 15916-11; 15457-11; 201274-11; 201893-11; 20461717

We kindly ask you to examine your inventory to determine if you have TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials.

We also kindly ask you to contact the final customers who may have the affected products and provide them with this letter.

Once the audit of your inventory and your final customers' inventory achieved, please sign and return the "Acknowledgment and Return Form" enclosed, by which you confirm that you have received this notification and you intend to fully comply with it.

With this form, you will ensure that all the devices TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials affected will be sent back including those already shipped to your customers when you will be contacted by Integra customer service during the first quarter 2018. You also confirm that this notification has been forwarded to every concerned customer.

Integra Customer Service will contact you upon availability of replacement units 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

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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
EMEA Compliance Coordinator

Enclosed: Acknowledgment and Return Form (1 page)

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ACKNOWLEDGMENT AND RETURN FORM

Medical devices:
TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials

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TRL092002506; TRL092002507; TRL092002508; TRL092002509; TRL092002510; TRL092002511; TRL092002512; TRL092002513; TRL092002514; TRL092002515; TRL092002516

Legal manufacturer:
Ascension Orthopedics, Inc. – 8700 Cameron road, Suite 100, Austin Texas 78754 USA

Concerned batch:
Lots listed in the letter

December 2017

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 notification regarding TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials.

I have transferred this letter to the persons to whom I have sold and/or place on consignment the concerned products. 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) will be sent back during the first quarter 2018 when I will be contacted by Integra customer service.

Please indicate quantity in the table below:

Description of affected product	Reference	Affected Lot Number	Quantity
TITAN™ Total Modular Shoulder System (TSS) Humeral Stem Trials	TRL092002506; TRL092002507; TRL092002508; TRL092002509; TRL092002510; TRL092002511; TRL092002512; TRL092002513; TRL092002514; TRL092002515; TRL092002516		

☐ **No**, I do not have the affected product in my inventory.

Distributor / Healthcare facility name

Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Signature

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