Stryker House, Hambridge Road
Newbury, Berkshire RG14 5AW
t: +44(0)1635 262400 f: +44(0)1635 580300
www.stryker.co.uk

stryker®
UK

«Contact_Name_»
«Customer_Name_»
«Address_1»
«Address_2»
«Town_»
«Postal_code_»
«Country_»

URGENT Field Safety Notice Update: RA 2013-083

20th November 2014

Dear Customer,

Description: Triathlon Tibial Alignment Ankle Clamp EM (Instrument)

Catalog No: 6541-2-609

Lot No: All

In August 2013, Stryker Orthopaedics initiated a Field Safety Corrective Action for the Triathlon Tibial Alignment Ankle Clamp EM, an instrument associated with the Triathlon Knee Instrumentation System. This action was initiated because Stryker had received customer complaints in which it was reported that the Triathlon Tibial Alignment Ankle Clamp had cracked or fractured. Please find enclosed a copy of the original communication which includes details on potential hazards and risk mitigation factors.

Please note that Stryker Orthopaedics has begun the planned transition of this action from a product bulletin to a product recall. In this second phase of the action, which will extend into 2015, we will replace all plastic (Rev. G) ankle clamps with metal (Rev. H) ankle clamps globally. Images of both clamps are provided below for reference. The product code for the clamp will not change.

Figure 1
Predicate Design
Triathlon Ankle Clamp (6541-2-609) Revision G

Figure 2
New Design
Triathlon Ankle Clamp (6541-2-609) Revision H

bsi.
RS11877

Immediate Actions

1. Immediately check your internal inventory and inspect all subject devices. Immediately quarantine any devices that show signs of cracking or fracture.

2. Circulate this Field Safety Notice internally to all interested / affected parties.

3. Maintain awareness of this notice internally until all required actions have been completed within your facility.

4. Inform Stryker if any of the subject devices have been distributed to other organisations.

    a) Please provide contact details so that Stryker can inform the recipients appropriately.

5. Complete the attached customer response form and return to Daniel Rana by fax (01635 262 464) or by e-mail (daniel.rana@stryker.com).

    a) Please complete this form even if you do not have any product to return. This will preclude the need for Stryker to send any reminder notice.

    b) On receipt of a completed customer response form, a Stryker representative will contact you to arrange collection and replacement of subject devices.

    c) A country specific replacement schedule is currently being coordinated by Stryker and replacements may not be available immediately. **However, please note that the plastic (Rev. G) ankle clamps can continue to be used in conjunction with the enclosed product bulletin dated August 2013 until replaced with metal (Rev. H) ankle clamps.**

6. Please inform Stryker of any adverse events concerning the use of the subject devices.

    a) Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

Stryker Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologise for any inconvenience this Field Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours faithfully,

Daniel Rana
Quality Assurance and Regulatory Affairs

RA 2013-083R: PFA Acknowledgement Form

Description: Triathlon Tibial Alignment Ankle Clamp EM (Instrument)

Catalog No: 6541-2-609

Lot No: All

I acknowledge receipt of the Field Safety Notice Update for RA 2013-083 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*			
We have located the following devices which require replacement:			
Product Description	**Product Reference**	**Lot Number**	**Qty**
We have further distributed subject devices to the following organisations:			
Facility Name			
Facility Address			

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Address	
Contact Name			
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464
OR EMAIL TO DANIEL.RANA@STRYKER.COM.

Upon receipt of a completed customer response form, a Stryker representative will be in touch to arrange collection and replacement of subject devices.