July 2013

RA2013-083: URGENT FIELD SAFETY NOTICE

Description: **Triathlon Tibial Alignment Ankle Clamp EM (Instrument)**

Catalog #: **6541-2-609**

Lot #: **All**

Dear Customer

Please find attached details of a Product Field Action that has been initiated by Stryker Orthopaedics concerning the above referenced devices. Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action. It may be that you no longer have any physical inventory on site. In this case you are receiving the notice because you have potentially received non-conforming devices in the past and as a responsible manufacturer we feel that it is our duty to ensure that you are aware of the information contained within the manufacturer's Field Safety Notice.

This action requires that you read the attached Field Safety Notice and complete the actions requested by the manufacturer that are detailed within this notice. We request that you then complete and return the attached customer response form to your local Stryker Distributor to confirm that you have received this notice.

Completing the Customer Response Form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete even if you no longer have any of the subject devices in your physical inventory.

We request that you respond to this notice within seven calendar days from the date of receipt. The target date for completion of this action is (insert date) and your timely response will enable us to ensure that we meet this target and ensure that the information has been shared with the appropriate parties.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:	Position:	E-mail:
Tel:	Fax:	

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours....

July 2013

RA2013-083: URGENT FIELD SAFETY NOTICE

Description: Triathlon Tibial Alignment Ankle Clamp EM (Instrument)

Catalog #: 6541-2-609

Lot #: All

Stryker® Orthopaedics has initiated a Field Safety Corrective Action for the Triathlon Tibial Alignment Ankle Clamp EM, an instrument associated with the Triathlon Knee Instrumentation System.

Issue

Stryker has received customer complaints in which it has been reported that the Triathlon Tibial Alignment Ankle Clamp has cracked or fractured.

Potential Hazards

The Triathlon Tibial Alignment Ankle Clamp EM cracks or fractures intraoperatively. The stability of the instrument is compromised. The following sequence of events may result:

A Triathlon TKA has progressed to the stage where proximal tibial resection is required to proceed with the surgery. The surgeon chooses to use Extramedullary (EM) referencing to ensure proper position and orientation of the proximal Tibial Resection Guide. The Ankle Clamp's Yoke or Flipper fractures prior to being attached to the ankle for EM referencing.

1. A sterile replacement Ankle Clamp is requested, located, and immediately available. The replacement Ankle Clamp is retrieved and the surgeon completes the remainder of surgery according to the established surgical technique.

   As a result, there is the potential for complications associated with extended surgery time of less than 5 minutes, the time required to retrieve the sterile replacement Ankle Clamp.

2. A sterile replacement Ankle Clamp is requested and located but not immediately available. The replacement Ankle Clamp is retrieved. The surgeon completes the remainder of surgery according to the established surgical technique.

   As a result, there is the potential for complications associated with extended surgery time of greater than or less than 30 minutes, the time required to retrieve the sterile replacement Ankle Clamp.

3. A sterile replacement Ankle Clamp is requested and is not available. The surgeon completes the positioning and alignment of the tibial resection guide using alternate intramedullary referencing instrumentation available within the kit. The proximal tibial

resection is completed using the IM referencing method and the surgery proceeds following the established surgical technique.

As a result, there is the potential for complications associated with extended surgery time of less than 30 minutes, the time required to complete proximal tibial resection using alternate intramedullary referencing (IM) method.

4. A sterile replacement Ankle Clamp is requested but is not located or immediately available. The surgeon notices the fractured instrument and makes a decision to use the instrument "as-is" with manual assistance for stabilization of the distal portion of the EM Tibial Resection Assembly. The surgeon completes the remainder of surgery according to the established surgical technique.

   As a result, there is the potential for complications associated with extended surgery time of less than 5 minutes, the time required to use the Ankle Clamp instrument with manual assistance for stabilization.

Patient Follow Up

There is no requirement to perform any additional patient monitoring or follow up. Should this event have occurred intraoperatively, the operating surgeon would have been immediately aware and undertaken appropriate measures to complete the surgery.

Device Usage

In the long term, Stryker will be replacing all of the above referenced devices. In the interim, customers may continue to use subject devices in conjunction with the information provided in the Product Correction Bulletin.

In accordance with the IFU for these devices (QIN 4382, Rev. D and instrument cleaning instructions provided by Stryker Orthopaedics (LSTPI-B, available at www.stryker.com/orthopaedics/cleaning)), please note that:

"**Functional checks should be performed at all times:**

- Mating devices should be checked for proper assembly.
- Instruments with moving parts should be operated to check correct operation..."

Risk Mitigation Factors

- In accordance with Triathlon Surgical Protocol (Literature# LSPK47), the surgeon could equally elect to use Intramedullary (IM) Instrumentation and referencing to ensure proper positioning and alignment. The Instrument for this is catalogue reference 65412600, IM Tibial Assembly Instrument.

- In the event of a fracture of the ankle clamp portion of the tibial alignment assembly at the flipper or at the yolk, the instrument will still function as intended with manual stabilization. See attached Product Correction Bulletin, figures 1 and 2.

Immediate actions

Please complete the following actions for all Triathlon EM Tibial Alignment Ankle Clamp Instruments in your possession.

1. Circulate this Field Safety Notice internally to all interested/affected parties.
2. Maintain awareness of this notice internally until all required actions have been completed within your facility.
3. Inform Stryker if any of the subject devices have been distributed to other organisations. *Please provide contact details so that Stryker can inform the recipients appropriately.*
4. Please inform Stryker of any adverse events.

   Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.
5. Complete the attached customer response form. *This will preclude the need for Stryker to send any unnecessary reminder notices.*
6. Return the completed form to your Stryker Distributor. The contact details are given on the customer response form.

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

If you have any further enquiries regarding this Field Safety Notice please do not hesitate to contact your designated Stryker Representative as indicated on the covering letter.

Yours Sincerely,

RA2013-083: CUSTOMER RESPONSE FORM

Description: Triathlon Tibial Alignment Ankle Clamp EM (Instrument)

Catalog #: 6541-2-609

Lot #: All

I acknowledge receipt of the Field Safety Notice for the above referenced action 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**	**Comments**
We have further distributed subject devices to the following organizations:				
Facility Name				
Facility Address				
Form completed by:				
Contact Name		**Contact Facility**		
Contact Address		**Contact Position**		
		Contact Tel No		
		Contact Fax No		
		Contact e-mail		

RA2013-08 Product Bulletin Triathlon Tibial Alignment Ankle Clamp

Issue: Stryker Orthopaedics has received complaints associated with cracks or fracture of the Triathlon Tibial Alignment Ankle Clamp.

As a result, there exists the potential for complications associated with extended surgery time of greater than thirty minutes to retrieve a replacement ankle clamp.

Field Safety Corrective Action Instructions: In the event of a fracture of the ankle clamp portion of the tibial alignment assembly at the flipper (figure 1) or at the yolk (figure 2), the instrument will still function as intended.

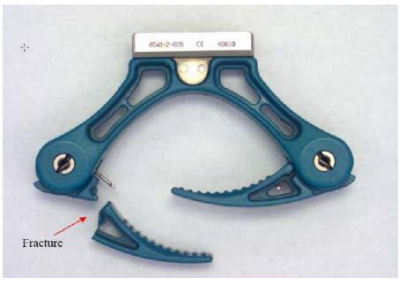

Figure 1

Figure 2

The process will remain the same as defined in the surgical protocol (ref. LSPK47 Rev5). Assemble the Tibial Alignment Ankle Clamp to the Tibial Alignment Distal Assembly EM. In case of a compromised Ankle Clamp, firmly hold the Tibial Alignment Distal Assembly EM and press up to/against the Tibia while maintaining alignment. In accordance with the Triathlon Surgical Protocol, flexion / extension alignment is correct when the long axis of the Tibial Resection Assembly parallels the mid-coronal plane of the tibia. Varus / Valgus alignment is similarly assessed per the established methods. (Figure 3)

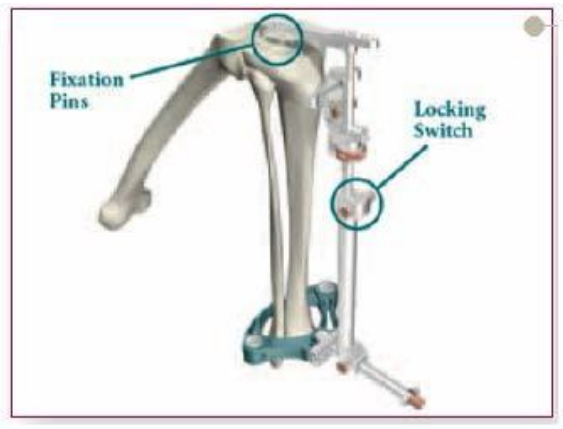

Figure 3

With a compromised ankle assembly, the surgeon would need to ensure the desired alignment is maintained by holding the assembly in place rather than relying on the stabilization of the ankle assembly. The tibial resection guide would then be pinned in place and the surgeon should proceed with the procedure per the protocol.

Should you have any queries on this issue please contact your local Stryker Distributor: Name – contact details