

September 17, 2014

**URGENT UPDATE: Field Safety Notice**

**FSCA identifier:** Product Field Action RA2013-083  
**Type of Action:** Field Safety Corrective Action  
**Description:** Triathlon Tibial Alignment Ankle Clamp EM (Instrument)  
**Catalog #:** 6541-2-609  
**Lot #:** All

Dear Distributor:

Please note that we have begun the planned transition of RA2013-083 from a Product Correction (see June 2013 Bulletin – lit. ref. TRIATH-BU-3) 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) clamps. Images of both clamps are provided below for reference.

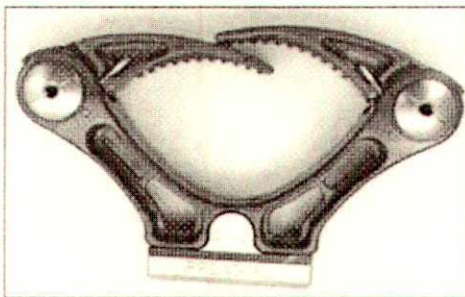


Figure 1  
Predicate Design  
Triathlon Ankle Clamp (6541-2-609) Revision G



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

**IMPORTANT:**

1. **Do not** return plastic clamps to Mahwah upon receipt of this message – a country-specific replacement schedule will be coordinated by the Knee Business Unit/International Customer Service. As a reminder, replacement activity will extend into 2015. A Stryker Brand Manager will contact your location to begin the exchange process as new design clamps become available.

2. Plastic (Rev. G) clamps can continue to be used in conjunction with the Product Correction Bulletin dated June 28, 2013, until replaced with metal (Rev. H) clamps.
3. The catalog number for the Clamp will not change.

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, please contact your local Sales Representative.

**Please refer all questions regarding replacement to the following individuals:**

Binu Jacob, Global Brand Manager Triathlon, Knee Marketing – 201-831-5390

Wanda Dipini, Account Lead, International Customer Service – 201-831-5541

Andrew Bone, Logistics and PLC Manager, Global Knee Marketing – 201-831-6146

Yours Sincerely,

RA2013-083

## Product Correction Bulletin

Triathlon Tibial Alignment Ankle Clamp

June 28, 2013

### **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.

### **Product Correction 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.

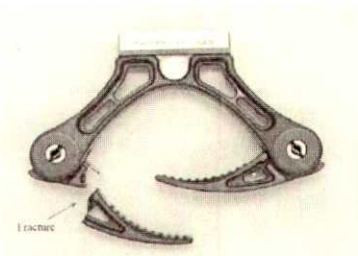


Figure 1



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)

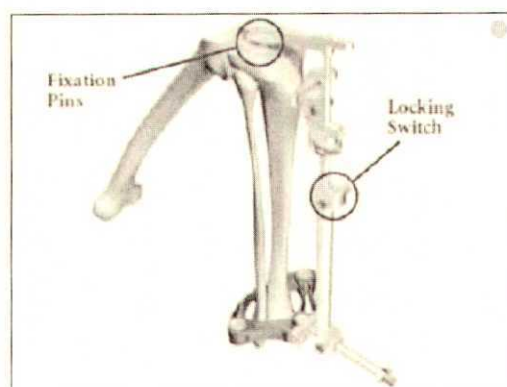


Figure 3

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.

Contact James Hept, Knee Marketing Team (Email: james.hept@stryker.com, Phone: 201-831-6414) with any questions regarding this bulletin.