

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,