

URGENT MEDICAL DEVICE CORRECTION

February 11, 2015

«ShipTo_Customer_Name»

«ShipTo_Address_1»

«ShipTo_Address_2_»

«SHIPTOCITY», «SHIPTOST» «SHIPTOZIP»

Product Correction #: RA 2014-169

Description: Triathlon Distal Capture Assembly

Catalog Number: 6541-1-723

Lot Code: Various – see attached list

Dear Customer

Stryker[®] Orthopaedics initiated a voluntary Product Correction (RA2014-169) for the Triathlon Distal Capture Assembly. This letter lists the known hazards potentially associated with the use of these products along with the risk mitigation factors.

Issue

Stryker Orthopaedics has received complaints regarding the disassociation of the cross pin from the action triggers of the Triathlon Distal Capture Assembly, part number 6541-1-723 which could lead to a loose or disassociated action trigger mechanism and/or loose or disassociated cross pin. Although using a capture for the distal femoral resection or proximal tibial resection in a Triathlon primary total knee arthroplasty is optional, if the surgeon elects to utilize a capture and such disassociation occurs, there exists the potential for the following harms:

- Complications associated with a delay in surgery of ≤15 minutes
- Revision surgery to retrieve loose component(s)
- Local Inflammatory response
- Inflammation
- Inflammatory Response

Risk Mitigation

See attached Product Correction Bulletin (RA2014-169).

Additionally, please note that Stryker is pursuing a long-term replacement plan for the Triathlon Distal Capture Assembly instruments currently located in the field.

Actions Required

Our records indicate that you may have received the above referenced product(s).

1. Immediately check your internal inventory and maintain a copy of this Field Safety Notice within the product.
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 and sign the enclosed "Acknowledgement of Receipt" form to confirm receipt of this notification and identify how many, if any, affected items are currently in your inventory. Please complete and return the acknowledgement receipt even if you don't have any affected product on hand and please send it by mail to (local email) _____ or by fax _____ (local contact)

Note: *Your signature on the Acknowledgement of Receipt indicates that you received and understand this Notification and have followed the instructions in this Notification*

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....

STRYKER[®] ORTHOPAEDICS

PRODUCT RECALL ACKNOWLEDGMENT FORM

Date:

Product Correction #: RA 2014-169

Description: Triathlon Distal Capture Assembly

Catalog Number: 6541-1-723

Lot Code: Various – see attached list

I have received the notification from Stryker[®] Orthopaedics dated _____ stating that they initiated a voluntary Product Recall of the product described above.

- NO, WE HAVE PHYSICALLY CHECKED OUR INVENTORY AND WE DO NOT HAVE THE AFFECTED PRODUCT(S).
- YES, WE HAVE SOME/ALL OF THE ITEMS REFERENCED IN THE ENCLOSED LETTER. WE HAVE _____ AFFECTED PRODUCT(S).

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND FAX TO
_____ **(local RAQA)**

Customer name

Stamp

RA2014-169

Product Correction Bulletin Triathlon Distal Capture Assembly

February XX, 2015

Issue:

Stryker Orthopaedics has received complaints regarding the disassociation of the cross pin from the action triggers of the Triathlon Distal Capture Assembly, part number 6541-1-723 which could lead to a loose or disassociated action trigger mechanism and/or loose or disassociated cross pin.

Although using a capture for the distal femoral resection or proximal tibial resection in a Triathlon primary total knee arthroplasty is optional, if the surgeon elects to utilize a capture and such disassociation occurs, there exists the potential for the following harms:

- Complications associated with a delay in surgery of ≤ 15 minutes
- Revision surgery to retrieve loose component(s)
- Local Inflammatory response
- Inflammation
- Inflammatory Response

Product Correction Instructions:

This section sets forth inspections that may prevent a distal capture with a nonconforming trigger mechanism from entering the operating room, thereby reducing the patient's exposure to the potential harms listed above.

Apply pressure and squeeze the Action Triggers on the Triathlon Distal Capture Assembly and visually inspect the cross pins to identify that the weld is properly maintaining the cross pin in the appropriate position*.

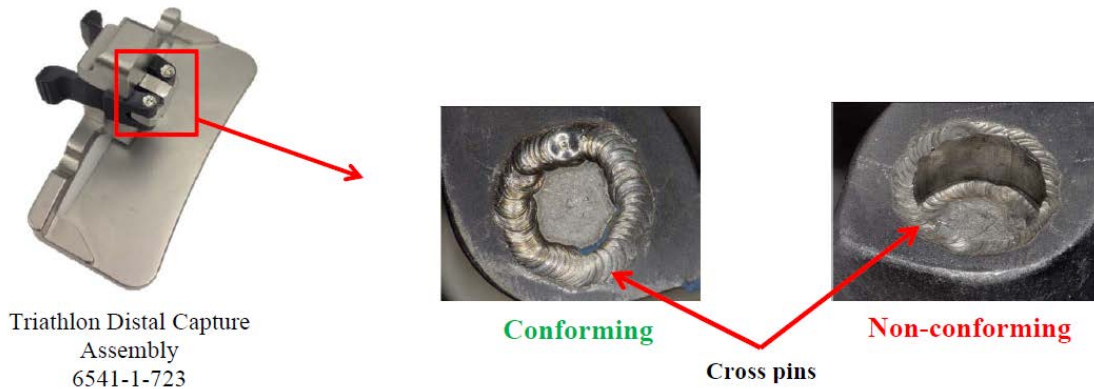


Figure 1

After confirming that the distal capture has a conforming trigger mechanism, the process for using the instrument will remain the same as defined in the surgical protocol (TRIATH-SP-3).

ER5ND5 ER6KA9 ER6ED8J ER7MA4E ER6EG5A

ER5NE4 ER6KD2 ER6EE2 ER7MA4T ER6KA1

ER5NE4M ER6KD5 ER6EE6 ER8SK2 ER6KA3

ER6CH1 ER6KD4 ER6EE1Y ER8SK2M ER6KA2

ER6CG9 ER6KD3 ER6EE7 ER8SK2P ER6KA4

ER6CH1A ER6KD6 ER6EE7J ER8SK3X ER6KA3A

ER6CH1M ER6KD7 ER6EE6M ER8SK3 ER6KA3T

ER6CH1D ER6MA3 ER6EF2 ER8SK4A ER6KA5

ER6ED1 ER6MA4 ER6EF3 ER8SK4 ER6KA7

ER6ED2 ER6SA3 ER6EF3A ER8SK4T ER6KA6

ER6ED1A ER6SA3J ER6EF4 ER8WA6 ER6KA7T

ER6ED3 ER6SA3X ER6EF5 ER8WA6P ER6KA8T

ER6ED5 ER7MA3 ER6EF4M ER8WA6X ER6KA8

ER6ED4 ER6SA4 ER6EF6 ER8WA9 ER6KD1

ER6ED7 ER7MA3M ER6EF6P ER8WA9P ER6EG5

ER6ED6 ER7MA3T ER6EF8 ER8WA9A ER9WA9

ER6ED7E ER7MA3D ER6EG3 ER9CH0 ER6EG4

ER6ED8 ER7MA4 ER6EG2 ER9CH0A ER9HR7

ER6ED9 ER7MA4A ER6EF9 ER9EA7

Affected Lot Numbers

*Inspection of reusable devices, as described in the Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices (Lit. # LSTPI-B Rev. 2, 08/12; Page 8) indicates that functional checks should be performed at all times. Mating devices should be checked for proper assembly and instruments with moving parts should be operated to check correct operation (medical grade lubricating oil suitable for steam sterilization can be applied as required).

Please contact _____ phone: _____
with any questions regarding this bulletin.