325 Corporate Drive
Mahwah, NJ 07430
t: 201-831-5000

stryker®
Orthopaedics

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 Branch/Agency,

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.

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Our records indicate that you may have received the above referenced product(s). Please assist us in meeting our regulatory obligation by returning the attached acknowledgement form confirming you have received and reviewed this bulletin:

Email to: StrykerOrtho3002@stericycle.com or Fax: 1-877-523-9106

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at (201) 831-6365.

Sincerely,

Christie Samsa
Associate Manager, Divisional Regulatory Compliance

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RA2014-169

List of affected lot numbers	
ER5ND5	ER6KA9
ER5NE4	ER6KD2
ER5NE4M	ER6KD5
ER6CH1	ER6KD4
ER6CG9	ER6KD3
ER6CH1A	ER6KD6
ER6CH1M	ER6KD7
ER6CH1D	ER6MA3
ER6ED1	ER6MA4
ER6ED2	ER6SA3
ER6ED1A	ER6SA3J
ER6ED3	ER6SA3X
ER6ED5	ER7MA3
ER6ED4	ER6SA4
ER6ED7	ER7MA3M
ER6ED6	ER7MA3T
ER6ED7E	ER7MA3D
ER6ED8	ER7MA4
ER6ED9	ER7MA4A
ER6ED8J	ER7MA4E
ER6EE2	ER7MA4T
ER6EE6	ER8SK2
ER6EE1Y	ER8SK2M
ER6EE7	ER8SK2P
ER6EE7J	ER8SK3X
ER6EE6M	ER8SK3
ER6EF2	ER8SK4A
ER6EF3	ER8SK4
ER6EF3A	ER8SK4T
ER6EF4	ER8WA6
ER6EF5	ER8WA6P
ER6EF4M	ER8WA6X
ER6EF6	ER8WA9
ER6EF6P	ER8WA9P
ER6EF8	ER8WA9A
ER6EG3	ER9CH0
ER6EG2	ER9CH0A
ER6EF9	ER9EA7
ER6EG4	ER9HR7
ER6EG5	ER9WA9
ER6EG5A	
ER6KA1	
ER6KA3	
ER6KA2	
ER6KA4	
ER6KA3A	
ER6KA3T	
ER6KA5	
ER6KA7	
ER6KA6	
ER6KA7T	
ER6KA8T	
ER6KA8	
ER6KD1	

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ACKNOWLEDGMENT FORM

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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 February 11, 2015 stating that they initiated a voluntary Product Correction for the above referenced product.

_____ _____
Surgeon, Hospital or Stryker® Orthopaedics Representative (Signature) Date

_____
Surgeon, Hospital or Stryker® Orthopaedics Representative (Print)

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL OR FAX LISTED BELOW:

- Email to: StrykerOrtho3002@stericycle.com or Fax: 1-877-523-9106