October 5th, 2015

URGENT: Field Safety Notice

FSCA identifier: Product Field Action RA2015-077

Type of Action: Field Safety Corrective Action: **Return to Supplier**

Description: Triathlon MIS Modular Distal Capture

Catalog #: 6541-5-723

Lot Code: AFZW21A, AFZW23R2, AF9L00A, AF8V03

Product owner: Howmedica Osteonics Corp., 325 Corporate Drive, Mahwah, NJ 07430, USA

Registration holder: Stryker Singapore Pte Ltd. 108 Pasir Panjang Road #03-04 Golden Agri Plaza Singapore 118535

Dear Distributor/Healthcare Professional:

On the 2nd of October 2015, Stryker initiated in Singapore a product recall for Triathlon MIS Modular Distal Capture devices as referenced above. The intent of this letter is to list all known hazards potentially associated with the use of the product and list the risk mitigation factors.

Intended use:

Instrument used in Total Knee Joint Replacement. The Triathlon MIS Distal Capture is used when a surgeon elects to use a capture for the distal femoral resection in a Triathlon primary MIS total knee arthroscopy. Once the Triathlon MIS Distal Resection Guide has been secured to the femur, the MIS distal capture can optionally be attached to the distal resection guide to complete the cut, per Triathlon MIS surgical protocol TRIATH-SP-5.

Issue:

Stryker has received customer complaints regarding Triathlon MIS Modular Distal Capture devices disassociating during use.

Potential Hazards:

1. Disassociated device

   The aforementioned potential hazard may result in one or more of the following potential patient harms:

1. Complications associated with extended surgery time of ≤ 15 min
2. Complications associated with extended surgery time of > 30 min.
3. Local inflammatory response
4. Inflammation.
5. Revision surgery to retrieve loose spring.
6. Inflammatory response.

Risk Mitigation

Inspection of reusable devices as described in Stryker Instructions for Cleaning, Sterilization, Inspection and Maintenance of Orthopaedic Medical Devices (LSTPI-B, Rev. 2) indicates that "instruments with moving parts should be operated to check correct operation". Additionally, the Instructions for Use (QIN 4382, Rev. D) states that "instruments with articulating surfaces must be tested for movement." Performing these inspections as instructed after cleaning may cause the device to disassociate prior to reaching the operating room. This may mitigate all of the hazardous situations.
.

Our records indicate that you have received the above referenced product. Please assist us in meeting our regulatory obligation by:

1. Immediately check your internal inventory and quarantine all subject devices.
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. *(Please provide contact details so that Stryker can inform the recipients appropriately).*
5. Complete the attached customer response form and return the form and any affected devices to your local Stryker Representative or via email of fax to sara.jato@stryker.com / fax: +84 (0)8 3827 5398..
   (Please complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice)

Reporting of Adverse Events

Please report any adverse events or product quality problems associated with this device to Stryker. Healthcare Professionals may also report any suspected adverse events associated with these devices to the Vigilance Branch, Health Products Regulation Group, HAS as indicated on www.hsa.gov.sg/ae_online by mail, fax or email to

Vigilance Branch
Health Products Regulation Group
11 Biopolis Way
#11-03 Helios
Singapore 138667
Fax: (65) 6478 9069
Email: HSA_productsafety@hsa.gov.sg
Tel: (65) 6866 3538

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 Safety Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please do not hesitate to contact the undersigned.

Yours Sincerely,

Sara Jato
QA Specialist
Stryker ASEAN
sara.jato@stryker.com
Tel. +84 (0)8 3827 5399 Ext.12

&

Amy Teo
Sales & Marketing Manager
Stryker Singapore Pte Ltd
amy.teo@stryker.com
Tel. 6500 9507

STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

October 5th, 2015

FACILITY

ADDRESS

CITY, STATE ZIP

FSCA identifier: Product Field Action RA2015-077

Type of Action: Field Safety Corrective Action: **Return to Supplier**

Description: Triathlon MIS Modular Distal Capture

Catalog #: 6541-5-723

Lot Code: AFZW21A, AFZW23R2, AF9L00A, AF8V03

Product owner: Howmedica Osteonics Corp., 325 Corporate Drive, Mahwah, NJ 07430, USA

Registration holder: Stryker Singapore Pte Ltd. 108 Pasir Panjang Road #03-04 Golden Agri Plaza Singapore 118535

I have received the notification from Stryker® Orthopaedics dated October 5th, 2015 stating that they initiated a Field Safety Corrective Action of the above referenced product.

_____ _____
Signature Date

_____
Name
(Print)

Please fax this signed and dated form to to sara.jato@stryker.com / +84 (0)8 3827 5398