September 11th 2015

URGENT: Field Safety Notice RA2014-170(EXT)

FSCA identifier: Product Field Action RA2014-170(EXT)

Type of Action: Field Safety Corrective Action: **Return to supplier.**

Description: LFIT V40 Tapers Vitallium Femoral Heads.

Catalog #: **6260-9-028, 6260-9-032 and 6260-9-132**

Lot #: See Appendix I

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 10th of September 2015 Stryker initiated in Singapore a voluntary product recall for specific lots of LFIT V40 Tapers Vitallium Femoral Heads 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:

Primary or revision total hip arthroplasty due to: Non-inflammatory degenerative arthritis (osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, pelvic fracture, failed fracture fixation, or diastrophic variant), or Inflammatory joint disease

Issue:

Stryker has received four customer complaints for LFIT V40 Vitallium femoral heads (manufactured July 7th 2014 – August 15th 2014) reporting that the femoral head could not be assembled with its corresponding V40 stem trunnion at the time of surgery. In each case a new V40 LFIT Vitallium femoral head was opened and used. No other adverse consequences or delays to surgery were reported for any of these complaints. .

The potential risks associated with this event are listed below.

Potential Hazards:

In the event that femoral head cannot be assembled with the stem trunnion or there exists inadequate locking strength between the head/stem taper interface there is a potential for:

1. Incorrect functionality – femoral head cannot be locked with stem trunnion.
2. Excessive soft tissue tension.
3. Insufficient soft tissue tension.
4. Inadequate locking strength – between the head/stem taper interface.
5. Excessive metallic wear debris.
6. Excessive metal ions: debris-related.
7. Excessive metal ions: corrosion-related.

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

1. Complications associated with extended surgery time of ≤15 minutes.
2. Loss of mobility, reduced range of motion.
3. Joint instability.
4. Loss of mobility, secondary to component disassociation.
5. Inflammatory response.
6. Revision surgery to correct the hazardous situation of joint instability.
7. Dislocation, secondary to joint instability.
8. Pain associated with implant loosening.
9. Adverse local tissue reaction.

Risk Mitigation

If the femoral head cannot be assembled with the stem trunnion, an alternate device of the same size/offset replacement femoral head should be used.

In the event there is inadequate locking strength between the head/stem taper interface, follow the surgical protocols for the products shown in Table 1, or another appropriate surgical protocol for use with a V40 femoral hip stem. Prior to final head assembly on the implanted stem trunnion, neck length and femoral head offset selection may be re-evaluated using a V40 femoral head trial.

The trial femoral head is placed on the stem trunnion and the hip is reduced to assess leg length equality and proper soft tissue tension. Performing this step may mitigate this potential hazard.

Also, per the surgical protocols for the products shown in **Table 1**, the femoral head is verified for proper assembly and taper lock during implantation. The protocols specify that the femoral head assembly is verified by applying traction to the femoral head and confirming stability on the stem trunnion. A femoral head that has not achieved a taper lock will be clearly evident during verification, thus reducing the occurrence of the implantation of an unlocked femoral head.

Note: **Table 1** includes a list of surgical protocols for several Stryker Hip Systems that may be used with V40 femoral hip stems, but it is not an exhaustive list.

Hip System name	Literature #
Accolade TMZF, Hfx, C	LASST
Accolade II Anato Secur-Fit Advanced	LSP76 LSP78 LSFFH-ST

Table 1: Examples of femoral hip stems with V40 trunnion and associated surgical protocol literature number.

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 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 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
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&

Amy Teo
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amy.teo@stryker.com
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Appendix I – List of affected products

Catalogue number	Lot Number
6260-9-028	48723404
6260-9-028	48799404
6260-9-032	48685304
6260-9-132	48699802
6260-9-132	48699805

STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

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I have received the notification from Stryker® Orthopaedics dated September 11th 2015 stating that they initiated a Field Safety Corrective Action of the above referenced product.

Affected products have been further distributed to: _____

_____

_____

Catalogue & lot number and quantity of affected products that have been returned to Stryker: ___

_____

Name: _____

Facility: _____

Position: _____

Address: _____

_____ _____

Signature Date

(Signature)