stryker
Orthopaedics

September XXth 2015

URGENT: Field Safety Notice

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

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

Description: LFIT V40 Tapers, V40 Tapers and PCA Tapers Vitallium Femoral Heads.

Catalog #: **6260-5-028, 6260-5-032, 6260-5-132, 6260-5-232, 6260-5-328, 6260-5-332, 6260-5-428, 6260-5-432, 6260-9-028, 6260-9-032, 6260-9-132, 6260-9-232, 6260-9-328, 6260-9-332, 6260-9-428, 6280-0-128, 6280-0-132, 6280-0-228, 6280-0-232 and 6280-0-332.**

Lot #: Various (as per distribution history)

Dear Distributor/ Risk Management/Surgeon:

On the XXth of September 2015 Stryker® Orthopaedics ("Stryker") initiated a voluntary product recall for specific lots of LFIT V40 Tapers, V40 Tapers and PCA 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.

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, a non-affected lot of V40 head 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 Instructions 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 Instructions for Use the femoral head is verified for proper assembly and taper lock during implantation. The femoral head assembly is verified by seating it firmly on the femoral component to prevent dissociation.
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.

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 to your local Stryker Representative.
6. Return any affected devices to your local Stryker Representative.
   (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)
7. Please inform Stryker of any adverse events associated with the use of the subject devices.
   a. Comply with any local regulations concerning the reporting of adverse events to local Competent Authorities.

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,

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STRYKER® ORTHOPAEDICS
FIELD SAFETY CORRECTIVE ACTION ACKNOWLEDGMENT FORM

September XX, 2015

SURGEON

ADDRESS

CITY, STATE ZIP

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Lot Code: Various (as per distribution history)

Type of Action: **Return to Supplier**

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

_____ _____

Surgeon (Signature) Date

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Surgeon (Print)