

## **URGENT Field Safety Notice: RA 2014-170(EXT)**

1<sup>st</sup> October 2015

**Description:** LFIT V40 Tapers, V40 Tapers and PCA Tapers Vitallium Femoral Heads  
**Product Code:** Please refer to the list on pages 4 and 5  
**Lot Number:** Please refer to the list on pages 4 and 5

Dear Customer,

Stryker Orthopaedics has initiated a Product Field Action for the devices identified in this FSN. The purpose of this letter is to list the hazards potentially associated with the Product Field Action.

### **Issue**

Stryker has received four customer complaints for LFIT V40 Vitallium femoral heads (manufactured July 7<sup>th</sup> 2014 – August 15<sup>th</sup> 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.

### **Potential Hazards**

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

1. Incorrect functionality – the femoral head cannot be locked with the stem trunnion.
2. Excessive soft tissue tension.
3. Insufficient soft tissue tension.
4. Inadequate locking strength between the head / stem interfaces.
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  $\leq 15$  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 loosening.
9. Adverse local tissue reaction.

**Risk Mitigation Factors**

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.

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

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

## **Actions Required**

1. Immediately check your internal inventory and quarantine any subject devices that are located.
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 the attached customer response form and return to Mark Fielding by fax (01635 262 464) or by e-mail ([mark.fielding@stryker.com](mailto:mark.fielding@stryker.com)).
  - a) Please complete this form even if you do not have any affected product. This will preclude the need for Stryker to send any reminder notice.
6. Upon receipt of a completed response form, a Stryker Representative will contact your facility to arrange collection of any affected devices that have been located on site.
7. Please inform Stryker of any adverse events concerning the use of the subject devices. Comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

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.

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

Yours faithfully,



Mark Fielding  
**Quality Assurance and Regulatory Affairs**

## Affected Product Codes and Lot Numbers

Product Code	Lot Numbers
6260-5-028	48734002, 48734001, 48734003, 48736502, 48750001, 48736503, 48750002, 48736504, 48736505, 48781102, 48736506, 48750004, 48781106, 48776401, 48781104, 48736501, 48776402, 48776403, 48776405, 48781101, 48776404, 48781105, 48776406, 48781103, 48734004, 49039302, 49042701, 49042702, 49042703, 49042704, 49054302, 49054303, 49054304, 49042705, 49039301, 49054301, 48750003
6260-5-032	48489002, 48489003, 48489004, 48681102, 48681103, 48685203, 48681101, 48685201, 48685202, 48863903, 48863901, 48863905, 48915602, 48866203, 48866206, 48878502, 48878503, 48915601, 48863902, 48863904, 48866201, 48866202, 48866204, 48866205, 48878501, 48878504, 48915603, 48915605, 48915606, 48915604, 49039202, 49039201, 49039203
6260-5-132	48683502, 48683503, 48683501, 48704103, 48704105, 48704101, 48704104, 48704106, 48704102, 48828802, 48817202, 48817203, 48828805, 48817201, 48817204, 48817205, 48828803, 48814503, 48828801, 48817206, 48828804, 48814501, 48814502, 48814505, 48923601, 48923602, 48995803, 48994705, 48923603, 48923604, 48923605, 48985704, 48985702, 48995804, 48985705, 48994703, 48985703, 48995801, 48994701, 48994704, 48995805, 48814504, 48994702, 48985701, 48985706, 48994706, 48995802
6260-5-232	48682302, 48682303, 48682301, 48689802, 48689801, 48845105, 48843401, 48845103, 48843402, 48843404, 48845102, 48843403, 48845104, 48847801, 48844002, 48859702, 48844001, 48845101, 48847802, 48845106, 48859701, 49032002, 49032003, 49032001
6260-5-328	48760501, 48760503, 48750102, 48760502, 48760504, 48750101, 48776302, 48776301, 49060402, 49060402
6260-5-332	48833301, 48833302, 48833303, 48894903, 48894904, 48894901, 48894902
6260-5-428	49054401, 49054402
6260-5-432	48878601, 48878602, 48894801, 48894802
6260-9-028	48723401, 48723404, 48723405, 48723406, 48733903, 48799401, 48799402, 48799404, 48799405, 48733904, 48733901, 48799403, 48723402, 48733902, 48723403, 48799406, 48974303, 48799407, 48799408, 48974306, 48948703, 48945203, 48945205, 48966201, 48966205, 48974301, 48974305, 48945202, 48948705, 48948706, 48966204, 48948704, 48966206, 48799409, 48945204, 48948702, 48966202, 48974307, 48974304, 48945201, 48974302, 48948701, 48966203
6260-9-032	48664103, 48681203, 48664104, 48638201, 48638202, 48638203, 48638204, 48664102, 48681201, 48685302, 48664101, 48685301, 48685303, 48685304, 48681202, 48914107, 48914105, 48914106, 48898802, 48914101, 48898804, 48914103, 48914102, 48914104, 48898801, 48898803
6260-9-132	48638102, 48638103, 48638104, 48638101, 48671501, 48671502, 48683602, 48671503, 48683603, 48683601, 48699801, 48699807, 48715102, 48715103, 48715105, 48719802, 48719803, 48715106, 48715104, 47615008R, 48699802, 48699805, 48715101, 48719801, 48699806, 48699803, 48699804, 48924601, 48946201, 48924604, 48999203, 48924603, 48999201, 48999202, 49011402, 49007003, 48924605, 49007002, 49007004, 49011403, 48947401, 49007006, 48924602, 48924606, 48944801, 48999204, 49007001, 49007005, 48944802, 49011401
6260-9-232	48655301, 48655303, 48617202, 48617203, 48620001, 48655304, 48617201, 48620003, 48655302, 48620002, 48671601, 48671602, 48682403, 48671603, 48689902, 48689903, 48682401, 48682402, 48847902, 48847903, 48689901, 48847904, 48847905, 48847906, 48847908, 48848002, 48848001, 48847907, 49032102, 49032103, 49032101
6260-9-328	48760002, 48776503, 48760001, 48760004, 48776502, 48760003, 48776501
6260-9-332	48620102, 48620101, 48620103, 48655401, 48655402, 48839301, 48843201,

	49011501, 49011502, 49011503
6260-9-428	48764405, 48764401, 48764403, 48765303, 48765304, 48764404, 48765302, 48764402, 48765301, 48762801
6280-0-128	48760201, 48760202
6280-0-132	49028701, 49028702
6280-0-228	48767201, 48767202
6280-0-232	49028601, 49028602
6280-0-332	49028301, 49028302

**RA 2014-170(EXT): PFA Acknowledgement Form**

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

**Product Code:** Please refer to the list on pages 4 and 5

**Lot Number:** Please refer to the list on pages 4 and 5

I acknowledge receipt of the Field Safety Notice for RA 2014-170(EXT) and can confirm that:

<b>We have not located any of these devices in our inventory:</b> <i>(please delete if not applicable)</i>			
<b>We have located the following devices:</b>			
Product Description	Product Reference	Lot Number	Qty
<b>We have further distributed subject devices to the following organisations:</b>			
Facility Name			
Facility Address			

<b>Please sign and return this form to acknowledge receipt of product notice.</b>			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

**PLEASE COMPLETE AND FAX THIS FORM TO 01635 262 464  
OR EMAIL TO [MARK.FIELDING@STRYKER.COM](mailto:MARK.FIELDING@STRYKER.COM).**