URGENT Field Safety Notice: RA 2016-028

LFIT™ Anatomic CoCr V40™ Femoral Heads

Reference number: RA2016-028

Description: LFIT™ Anatomic CoCr V40™ Femoral Heads

Product Code: 6260-9-236, 6260-9-240, 6260-9-244, 6260-9-340, 6260-9-344, 6260-9-440, 6260-9-444

Lot Number: All lots manufactured between 01 January 2002 and 04 March 2011

Dear Customer,

Stryker has initiated a voluntary medical device product field action for the following Femoral Heads.

The intent of this letter is to describe all potential hazards associated with the below noted issue, and any risk mitigation factors associated with the use of the product.

Our records indicate that you have received the above referenced product. It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication.

Reason for the Voluntary Product Field action:

Stryker has received higher than expected complaints of taper lock failure for specific lots of the following certain sizes of LFIT™ Anatomic CoCr V40TM Femoral Heads manufactured prior to 2011.

Catalog Number	Head Diameter	Offset
6260-9-236	36mm	+5
6260-9-240	40mm	+4
6260-9-244	44mm	+4
6260-9-340	40mm	+8
6260-9-440	40mm	+12
6260-9-344	44mm	+8
6260-9-444	44mm	+12

Potential Hazards may include:

- Disassociation of femoral head from hip stem
- Fractured hip stem trunnion
- Excessive metallic debris
- Insufficient ROM
- Insufficient soft tissue tension

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- Noise
- Loss of implant: bone fixation strength
- Excessive wear debris (polymeric)
- Implant construct with a shortened neck length

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

- User annoyance
- Loss of mobility
- Pain requiring revision
- Inflammatory response
- Adverse local tissue reaction
- Dislocation
- Joint instability
- Revision to alleviate hazardous situation
- Pain associated with implant loosening
- Periprosthetic fracture
- Leg length discrepancy

Follow up:

Implanted patients with LFIT™ Anatomic CoCr V40™ Femoral Heads as described above should continue to be followed per the normal protocol established by his/her surgeon.

Required actions:

Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Please be aware that all affected products are either expired or already implanted. Check your internal inventory and in case you still have any product, quarantine all subject devices pending return to Stryker.

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.
    b) If you are a Distributor, note that you are responsible for notifying your affected customers.

5. Please inform Stryker of any adverse events concerning the use of the subject devices.
    a) Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

6. Complete the attached customer response form. Please complete even if you no longer have any of the subject devices in your physical inventory.

7. Return the completed form to Stryker using the details provided at the end of the reply form.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Tom Baker
Position: Senior Product Manager
Telephone: 01635 556517
E-mail: tom.baker@stryker.com

We request that you respond to this notice within 07 calendar days from the date of receipt.

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date 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.

Yours faithfully,

Nina Goddard
Regulatory Affairs and Quality Assurance

RA 2016-028: PFA Acknowledgement Form

I acknowledge receipt of the Field Safety Notice for RA 2016-028 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*	

We have located the following devices:			
Product Description	**Product Reference**	**Lot Number**	**Qty**

We have further distributed subject devices to the following organisations:	
Facility Name	
Facility Address	

Please sign and return this form to acknowledge receipt of product notice.			
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 NINA.GODDARD@STRYKER.COM