URGENT MEDICAL DEVICE
PRODUCT FIELD ACTION NOTIFICATION
LFIT™ Anatomic CoCr V40™ Femoral Heads

August 29, 2016

Product Field Action Number:	RA2016-028
Description:	LFIT™ Anatomic CoCr V40™ Femoral Heads
Catalog Number(s):	6260-9-236, 6260-9-240, 6260-9-244, 6260-9-340, 6260-9-344, 6260-9-440, 6260-9-444
Lot Code(s):	See attached

Dear XXX,

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
- 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 your nominated Stryker Representative (indicated below) for this PFA

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: Position: email:

We request that you respond to this notice within **XXX** calendar days from the date of receipt. The target date for completion of this action is **XXX** and your timely response will enable us to ensure that we meet this target.

Should you have any question related to this recall, please find below the contact for your country:

- Local PM email and desk phone
- Local RAQA manager Email and desk phone"

Additionally, Stryker Corporation has established a dedicated call center in the US that works for calls from Europe at 1-978-338-3143. Please be advised that the service hours will be according to the US time zone and the language spoken will be English.

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....

Sincerely,

URGENT MEDICAL DEVICE
RECALL NOTIFICATION
LFIT™ Anatomic CoCr V40™ Femoral Heads

August 29, 2016

Product Field Action Number:	RA2016-028
Description:	LFIT™ Anatomic CoCr V40™ Femoral Heads
Catalog Number(s):	6260-9-236, 6260-9-240, 6260-9-244, 6260-9-340, 6260-9-344, 6260-9-440, 6260-9-444
Lot Code(s):	See attached

I have received the product recall letter from Stryker dated August 29, 2016 stating that the company has initiated a voluntary, lot-specific product recall of the above referenced product.

_____ _____

Stryker Branch / Agent / Hospital Representative (Signature) Date

_____ _____

Stryker Branch / Agent / Hospital Representative (Print) Stryker Branch / Agency/Hospital Name

PLEASE COMPLETE THIS FORM WITHIN 5 BUSINESS DAYS AND RETURN IT BY USING THE EMAIL OR FAX LISTED BELOW:

email: strykerortho8402@stericycle.com
fax: **888-912-8457**