stryker

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

Dear Surgeon,

Stryker has initiated a voluntary medical device recall 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 Recall:
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:

1. Hospitals/Surgeons: Please inform users of this Urgent Medical Device Recall Notification and forward this notice to all those individuals who need to be aware within your organization. Complete and sign the enclosed Business Reply Form and fax a copy to **1-888-912-8457** or email to Stericycle at strykerortho8402@stericycle.com

2. Stryker Branches/Agencies: No product is to be returned as part of this notification.

Our records indicate that you have received the above referenced product. It is our responsibility to ensure that customers who may have received this affected product also receive this important communication. **Please assist us in meeting our regulatory obligation by faxing back the attached Business Reply Form within 5 days of receipt of this letter.**

For patient questions, Stryker has established a dedicated call center at 1-888-644-2548.

We regret any inconvenience this action may cause you and if you have any questions, feel free to contact me at 1-201- 831-6693.

Sincerely,

Eric Petschler
Manager, Regulatory Compliance