stryker

PRODUCT SAFETY NOTIFICATION

May 22, 2018

Product Field Action Number:	1757583
Description:	**LFIT™ Anatomic CoCr V40™ Femoral Heads**
Catalog Number(s):	6260-9-036, 6260-9-136, 6260-9-236, 6260-9-336, 6260-9-040, 6260-9-140, 6260-9-044, 6260-9-144
Lot Code(s):	See attached

Dear Customer,

Stryker would like to inform you of an important Safety Notification related to the products referenced above and described in further detail in the table below (the "Products"). Our records indicate that you have received one or more of the Products. It is Stryker's responsibility, as the manufacturer, to ensure that customers who may have received any of the Products also receive this important notification.

Background

Stryker has received a higher than expected number of complaints documenting femoral head/hip stem dissociation for certain sizes of LFIT™ Anatomic CoCr V40™ Femoral Heads manufactured *prior to* March 4, 2011.

With respect to the likelihood of occurrence of femoral head/hip stem dissociation, the complaint rate is less than 0.3% for the Products within the scope of this notification.

The following table lists the specific Products that are within scope of this notification:

Catalog number	Head diameter	Offset
6260-9-036	36mm	-5
6260-9-136	36mm	+0
6260-9-236	36mm	+5
6260-9-336	36mm	+10
6260-9-040	40mm	-4
6260-9-140	40mm	+0
6260-9-044	44mm	-4
6260-9-144	44mm	+0

Please note that the following clinical conditions may potentially be related to femoral head/hip stem dissociation.

- Dislocation
- Pain associated with implant loosening
- Peri-prosthetic fracture
- Revision to alleviate hazardous situation
- Leg length discrepancy
- Loss of mobility secondary to hip/stem trunnion fracture or femoral head/hip stem dissociation
- Pain requiring revision surgery
- Inflammatory response
- Adverse local tissue reaction (ALTR)

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Follow-up

Patients implanted with the Products should continue to be followed per the normal protocol established by his/her surgeon(s). There are no recommended changes to the frequency of the standard follow-up care protocol.

Required actions

1. Hospitals/Surgeons: Please inform product users of this notification and forward this notice to all those individuals who need to be aware within your organization. Please also complete and sign the enclosed Business Reply Form and fax a copy to **888-861-8582** or email to Stericycle at strykerortho5940@stericycle.com. Product is not required to be returned as part of this notification.

2. Stryker Branches/Agencies: Product is not required to be returned as part of this notification.

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 situation may cause you and if you have any questions, feel free to contact me at (201) 831-5151.

Sincerely,

Stan Dube
Director, Post Market Regulatory Compliance

PRODUCT SAFETY NOTIFICATION
BUSINESS REPLY FORM

May 22, 2018

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Lot Code(s):	See attached

I have received the Product Safety Notification from Stryker dated May 22, 2018.

Stryker's Branch / Agent / Hospital Representative (Signature)	Date
Stryker's Branch / Agent / Hospital Representative (Print)	Stryker's Branch / Agency/Hospital Name

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

email: strykerortho5940@stericycle.com
fax: **888-861-8582**