

**PRODUCT SAFETY NOTIFICATION
RA2018-1757583**

Type of action: Safety Notification
Action Ref: RA2018-1757583
Description: LFIT™ Anatomic CoCr V40™ Femoral Heads
References: 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 numbers: see attached
Legal Manufacturer: Howmedica Osteonics Corp. 325 Corporate Drive. 07430. Mahwah. N.J.

May xx, 2018

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)

Follow-up

Stryker do not recommend any changes to the frequency of the standard follow-up care protocol for patients implanted with the affected lots of the LFIT Anatomic CoCr V40 Femoral Heads manufactured prior to March 04, 2011, as described above. Patient's should continue to be followed up as per the normal treatment protocol established by his/her surgeon based on the surgeon's independent medical and clinical judgment, experience and training, knowledge of the individual patient and the patient's clinical presentation, and the standard of care for their specific region or country.

Complaints of new or continued pain, stiffness, instability or swelling in the hip, groin, buttock or thigh warrant further investigation. This could include hematologic and chemistry lab work (CBC with differential, ESR, C - reactive protein, and metal ion analysis), as well as joint aspiration and synovial fluid analysis (cell count differential, culture sensitivity, metal-ion analysis). Possible mechanical causes of these symptoms could be evaluated with an MRI, CT or Bone Scan.

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.
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

PRODUCT SAFETY NOTIFICATION
RA2018-1757583
ACKNOLEGEMENT FORM

Type of action: Safety Notification
Action Ref: RA2018-1757583
Description: LFIT™ Anatomic CoCr V40™ Femoral Heads
References: 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 numbers: See attached

I acknowledge receipt of the Field Safety Notice for RA2018-1757583 and can confirm that:

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

Hospital Name _____ **Contact name** _____
Facility Stamp _____ **Contact Position** _____
_____ **Contact Tel No** _____
_____ **Contact e-mail** _____

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

email:
fax:

Item	Lot	Item	Lot	Item	Lot	Item	Lot	Item	Lot
6260-9-236	MJRAKL	6260-9-236	MJTW08	6260-9-236	MKD717	6260-9-236	MKD853	6260-9-236	MKE18M
6260-9-236	MJRBANR	6260-9-236	MJTX6W	6260-9-236	MKD854	6260-9-236	MKD855	6260-9-236	MKE19M
6260-9-236	MJREIT	6260-9-236	MJTX7K	6260-9-236	MKD856	6260-9-236	MKD857	6260-9-236	MKE20M
6260-9-236	MJRED7	6260-9-236	MJTY26	6260-9-236	MKD858	6260-9-236	MKD859	6260-9-236	MKE21M
6260-9-236	MJREPY	6260-9-236	MJTY9Y	6260-9-236	MKD860	6260-9-236	MKD861	6260-9-236	MKE22M
6260-9-236	MJRH3T	6260-9-236	MJTYL0	6260-9-236	MKD862	6260-9-236	MKD863	6260-9-236	MKE23M
6260-9-236	MJRH70	6260-9-236	MJTYWX	6260-9-236	MKD864	6260-9-236	MKD865	6260-9-236	MKE24M
6260-9-236	MJRH8H	6260-9-236	MKA00J	6260-9-236	MKD866	6260-9-236	MKD867	6260-9-236	MKE25M
6260-9-236	MJRHDX	6260-9-236	MKA06L	6260-9-236	MKD868	6260-9-236	MKD869	6260-9-236	MKE26M
6260-9-236	MJRU37	6260-9-236	MKA0AD	6260-9-236	MKD870	6260-9-236	MKD871	6260-9-236	MKE27M
6260-9-236	MJRU60	6260-9-236	MKA120	6260-9-236	MKD872	6260-9-236	MKD873	6260-9-236	MKE28M
6260-9-236	MJRU9M	6260-9-236	MKA1N4	6260-9-236	MKD874	6260-9-236	MKD875	6260-9-236	MKE29M
6260-9-236	MJRUJL	6260-9-236	MKA2V9	6260-9-236	MKD876	6260-9-236	MKD877	6260-9-236	MKE30M
6260-9-236	MJRUJM	6260-9-236	MKA3A9	6260-9-236	MKD878	6260-9-236	MKD879	6260-9-236	MKE31M
6260-9-236	MJRK2P	6260-9-236	MKA45W	6260-9-236	MKD880	6260-9-236	MKD881	6260-9-236	MKE32M
6260-9-236	MJRKEN	6260-9-236	MKA4X4	6260-9-236	MKD882	6260-9-236	MKD883	6260-9-236	MKE33M
6260-9-236	MJRKW3	6260-9-236	MKA500	6260-9-236	MKD884	6260-9-236	MKD885	6260-9-236	MKE34M
6260-9-236	MJRNVA	6260-9-236	MKA54D	6260-9-236	MKD886	6260-9-236	MKD887	6260-9-236	MKE35M
6260-9-236	MJRNHN	6260-9-236	MKA5T2	6260-9-236	MKD888	6260-9-236	MKD889	6260-9-236	MKE36M
6260-9-236	MJRE3N	6260-9-236	MKA6E8	6260-9-236	MKD890	6260-9-236	MKD891	6260-9-236	MKE37M
6260-9-236	MJRTL2	6260-9-236	MKA714	6260-9-236	MKD892	6260-9-236	MKD893	6260-9-236	MKE38M
6260-9-236	MJRTF7	6260-9-236	MKA76T	6260-9-236	MKD894	6260-9-236	MKD895	6260-9-236	MKE39M
6260-9-236	MJRVHD	6260-9-236	MKA882	6260-9-236	MKD896	6260-9-236	MKD897	6260-9-236	MKE40M
6260-9-236	MJRVMM	6260-9-236	MKA903	6260-9-236	MKD898	6260-9-236	MKD899	6260-9-236	MKE41M
6260-9-236	MJRWOK	6260-9-236	MKA972	6260-9-236	MKD900	6260-9-236	MKD901	6260-9-236	MKE42M
6260-9-236	MJRW87	6260-9-236	MKA98X	6260-9-236	MKD902	6260-9-236	MKD903	6260-9-236	MKE43M
6260-9-236	MJRX01	6260-9-236	MKA9A5	6260-9-236	MKD904	6260-9-236	MKD905	6260-9-236	MKE44M
6260-9-236	MJRYMD	6260-9-236	MKAA45	6260-9-236	MKD906	6260-9-236	MKD907	6260-9-236	MKE45M
6260-9-236	MJRYOJ	6260-9-236	MKAD0V	6260-9-236	MKD908	6260-9-236	MKD909	6260-9-236	MKE46M
6260-9-236	MJTO3J	6260-9-236	MKAD3R	6260-9-236	MKD910	6260-9-236	MKD911	6260-9-236	MKE47M
6260-9-236	MJTOXL	6260-9-236	MKAD3R	6260-9-236	MKD912	6260-9-236	MKD913	6260-9-236	MKE48M
6260-9-236	MJT2PD	6260-9-236	MKADKW	6260-9-236	MKD914	6260-9-236	MKD915	6260-9-236	MKE49M
6260-9-236	MJT2RP	6260-9-236	MKADL8	6260-9-236	MKD916	6260-9-236	MKD917	6260-9-236	MKE50M
6260-9-236	MJT3L3	6260-9-236	MKADL8	6260-9-236	MKD918	6260-9-236	MKD919	6260-9-236	MKE51M
6260-9-236	MJT3SH	6260-9-236	MKAE41	6260-9-236	MKD920	6260-9-236	MKD921	6260-9-236	MKE52M
6260-9-236	MJT46E	6260-9-236	MKAE1X	6260-9-236	MKD922	6260-9-236	MKD923	6260-9-236	MKE53M
6260-9-236	MJTERX	6260-9-236	MKA779	6260-9-236	MKD924	6260-9-236	MKD925	6260-9-236	MKE54M
6260-9-236	MJT6PK	6260-9-236	MKA8RT	6260-9-236	MKD926	6260-9-236	MKD927	6260-9-236	MKE55M
6260-9-236	MJT6PK	6260-9-236	MKA8V5	6260-9-236	MKD928	6260-9-236	MKD929	6260-9-236	MKE56M
6260-9-236	MJT6Y3	6260-9-236	MKA933	6260-9-236	MKD930	6260-9-236	MKD931	6260-9-236	MKE57M
6260-9-236	MJT7DY	6260-9-236	MKA9M4	6260-9-236	MKD932	6260-9-236	MKD933	6260-9-236	MKE58M
6260-9-236	MJT7RN	6260-9-236	MKAN4V	6260-9-236	MKD934	6260-9-236	MKD935	6260-9-236	MKE59M
6260-9-236	MJT7V9	6260-9-236	MKANZL	6260-9-236	MKD936	6260-9-236	MKD937	6260-9-236	MKE60M
6260-9-236	MJT8LR	6260-9-236	MKAN56	6260-9-236	MKD938	6260-9-236	MKD939	6260-9-236	MKE61M
6260-9-236	MJT8LR	6260-9-236	MKANP39	6260-9-236	MKD940	6260-9-236	MKD941	6260-9-236	MKE62M
6260-9-236	MJT8LK	6260-9-236	MKANR0X	6260-9-236	MKD942	6260-9-236	MKD943	6260-9-236	MKE63M
6260-9-236	MJTEVE	6260-9-236	MKANR81	6260-9-236	MKD944	6260-9-236	MKD945	6260-9-236	MKE64M
6260-9-236	MJTEVE	6260-9-236	MKANR81	6260-9-236	MKD946	6260-9-236	MKD947	6260-9-236	MKE65M
6260-9-236	MJTHAX	6260-9-236	MKARWR	6260-9-236	MKD948	6260-9-236	MKD949	6260-9-236	MKE66M
6260-9-236	MJTH77	6260-9-236	MKAVMR	6260-9-236	MKD950	6260-9-236	MKD951	6260-9-236	MKE67M
6260-9-236	MJTHVP	6260-9-236	MKAXT9	6260-9-236	MKD952	6260-9-236	MKD953	6260-9-236	MKE68M
6260-9-236	MJTJDA	6260-9-236	MKAXYV	6260-9-236	MKD954	6260-9-236	MKD955	6260-9-236	MKE69M
6260-9-236	MJTKDA	6260-9-236	MKAXYV	6260-9-236	MKD956	6260-9-236	MKD957	6260-9-236	MKE70M
6260-9-236	MJTKKM	6260-9-236	MKAXYV	6260-9-236	MKD958	6260-9-236	MKD959	6260-9-236	MKE71M
6260-9-236	MJTLOH	6260-9-236	MKAXYV	6260-9-236	MKD960	6260-9-236	MKD961	6260-9-236	MKE72M
6260-9-236	MJTLE8	6260-9-236	MKD01T	6260-9-236	MKD962	6260-9-236	MKD963	6260-9-236	MKE73M
6260-9-236	MJTLE8	6260-9-236	MKD05N	6260-9-236	MKD964	6260-9-236	MKD965	6260-9-236	MKE74M
6260-9-236	MJTLE8	6260-9-236	MKD0DA	6260-9-236	MKD966	6260-9-236	MKD967	6260-9-236	MKE75M
6260-9-236	MJTIMP7	6260-9-236	MKD0N3	6260-9-236	MKD968	6260-9-236	MKD969	6260-9-236	MKE76M
6260-9-236	MJTIMY5	6260-9-236	MKD0Z6	6260-9-236	MKD970	6260-9-236	MKD971	6260-9-236	MKE77M
6260-9-236	MJTN0T	6260-9-236	MKD1R8	6260-9-236	MKD972	6260-9-236	MKD973	6260-9-236	MKE78M
6260-9-236	MJTP1R	6260-9-236	MKD185	6260-9-236	MKD974	6260-9-236	MKD975	6260-9-236	MKE79M
6260-9-236	MJTP4D	6260-9-236	MKD2AA	6260-9-236	MKD976	6260-9-236	MKD977	6260-9-236	MKE80M
6260-9-236	MJTPE2	6260-9-236	MKD3MX	6260-9-236	MKD978	6260-9-236	MKD979	6260-9-236	MKE81M
6260-9-236	MJTR46	6260-9-236	MKD3PK	6260-9-236	MKD980	6260-9-236	MKD981	6260-9-236	MKE82M
6260-9-236	MJTR48	6260-9-236	MKD456	6260-9-236	MKD982	6260-9-236	MKD983	6260-9-236	MKE83M
6260-9-236	MJTRAP	6260-9-236	MKD4AR	6260-9-236	MKD984	6260-9-236	MKD985	6260-9-236	MKE84M
6260-9-236	MJTRY7	6260-9-236	MKD4NE	6260-9-236	MKD986	6260-9-236	MKD987	6260-9-236	MKE85M
6260-9-236	MJTTKL	6260-9-236	MKD4XE	6260-9-236	MKD988	6260-9-236	MKD989	6260-9-236	MKE86M
6260-9-236	MJTTI3	6260-9-236	MKD51M	6260-9-236	MKD990	6260-9-236	MKD991	6260-9-236	MKE87M
6260-9-236	MJTV44	6260-9-236	MKD59R	6260-9-236	MKD992	6260-9-236	MKD993	6260-9-236	MKE88M
6260-9-236	MJTV6V	6260-9-236	MKD5R5	6260-9-236	MKD994	6260-9-236	MKD995	6260-9-236	MKE89M
6260-9-236	MJTVNK	6260-9-236	MKD5W8	6260-9-236	MKD996	6260-9-236	MKD997	6260-9-236	MKE90M
6260-9-236	MJTVRE	6260-9-236	MKD63H	6260-9-236	MKD998	6260-9-236	MKD999	6260-9-236	MKE91M
6260-9-236	MJTVRJ	6260-9-236	MKD6TR	6260-9-236	MKD999	6260-9-236	MKD999	6260-9-236	MKE91M
6260-9-236	MJTVY8	6260-9-236	MKD6WT	6260-9-236	MKD999	6260-9-236	MKD999	6260-9-236	MKE91M
6260-9-236	MJTW5E	6260-9-236	MKD7AR	6260-9-236	MKD999	6260-9-236	MKD999	6260-9-236	MKE91M