ZIMMER BIOMET

28 February 2023

To: Hospitals and Surgeons

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (CORRECTION)**

Affected Product: CoCr Femoral Head, XS, 38/-8, Taper 12/14

Item Number	Lot Number	GTIN Number
01.01012.384	All Lots	00889024283268

Zimmer GmbH is conducting a medical device Field Safety Corrective Action (correction) to update the compatibility matrix as referred to in the Instructions for Use (IFU) for the CoCr Femoral Head XS. The update is to remove the compatibility with the Epsilon Durasul Constrained Acetabular Liners from the matrix due to the range of motion in flexion/extension being less than 100 degrees as recommended per an internationally recognized standard (ISO 21535:2009). When used in combination with the Epsilon Durasul Constrained Acetabular Liner, the CoCr Femoral Head XS has a range of motion of 76 degrees. The reduced range of motion could potentially result in the health risks identified in the table below. There have been no complaints for this issue.

You are receiving this letter because our records indicate that you have implanted the CoCr Femoral Head XS in combination with an Epsilon Durasul Constrained Liner. For your reference, the Epsilon Durasul Constrained Liner part numbers are provided in Appendix 1.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None.	None.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None.	Events may occur, such as impingement, instability, or dislocation, leading to revision surgery.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between August 2000 and April 2019. Local deployment may differ.

ZFA2022-00302

Hospital Responsibilities:

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. Complete **Attachment 1 – Certificate of Acknowledgement Form** and send to fieldaction.gscc@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
3. Retain a copy of the **Attachment 1 – Certificate of Acknowledgement Form** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
4. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this Field Safety Notice for awareness of the contents.
2. There are no specific patient monitoring instructions related to this Field Safety Corrective Action that are recommended beyond your existing follow-up schedule.
3. Complete **Attachment 1 – Certificate of Acknowledgement Form** and send to fieldaction.gscc@zimmerbiomet.com.
4. Retain a copy of the **Attachment 1 – Certificate of Acknowledgement Form** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your local Zimmer Biomet representative.

Other Information

This medical device Field Safety Corrective Action was reported to all relevant Competent Authorities and related Notified Bodies as required under the applicable regulations for Medical Devices per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing ProductComplaintGSCC@zimmerbiomet.com.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies.

We would like to thank you for your co-operation and regret any inconvenience caused by this Field Safety Corrective Action.

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ATTACHMENT 1 - Certificate of Acknowledgement Form

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: CoCr Femoral Heads
Field Safety Corrective Action Reference: ZFA2022-00302

Certificate of Acknowledgement

By signing below, I acknowledge that I have received, read and understood the contents of this Field Safety Notice. All required actions are complete or are being completed.

Please check one as applicable: ☐ Hospital Facility ☐ Surgeon

Printed Name:_____ **Signature:**_____

Title:_____ **Telephone:**_____ **Date:**_____

Facility Name:_____

Facility Address:_____

City:_____ **Country:**_____ **ZIP/Post Code:**_____

Please return the completed form to your Zimmer Biomet contact or by e-mail to fieldaction.gscc@zimmerbiomet.com.

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APPENDIX 1: Epsilon Durasul Constrained Acetabular Liners Item Numbers (for reference only)

Item Number	GTIN Number	Description
4380-38-061	00889024169678	EPSILON DURASUL CONSTR LINER SZ 38X61MM
4380-38-063	00889024169685	EPSILON DURASUL CONSTR LINER SZ 38X63MM
4380-38-065	00889024169692	EPSILON DURASUL CONSTR LINER SZ 38X65MM
4380-38-067	00889024169708	EPSILON DURASUL CONSTR LINER SZ 38X67MM
4380-38-069	00889024169715	EPSILON DURASUL CONSTR LINER SZ 38X69MM
4380-38-071	00889024169722	EPSILON DURASUL CONSTR LINER SZ 38X71MM