ZIMMER BIOMET

February 13, 2017

To: Distributors

Subject: **URGENT FIELD SAFETY NOTICE - INFORMATION**

FSN/FSCA: **FA 2016-10 (ZFA 2016-150)**

Affected Products: Metal heads (manufactured either in cobalt chromium alloys such as Modular femoral heads and Metasul heads or in stainless steels such as Protasul S 30 femoral heads)

Metal heads	Manufacturer	Part number
Modular femoral heads (CoCr)	Zimmer GmbH	all
Protasul® S30 femoral heads	Zimmer GmbH	all
Metasul® heads	Zimmer GmbH	all

that can be used in a metal on polyethylene combination with following devices systems: Alloclassic Variall Screw Cup, Alloclassic Zweymüller CSF Screw Cup, Allofit Shell, Allofit IT Shell, CLS Spotorno Shell, Fitmore Shell, Müller Low Profile Cup, and Stafit Double Mobility.

Dear Distributor,

With regards to the use of metal heads after ceramic component breakage, Zimmer GmbH would like to remind you, by means of this Field Safety Notice, about the appropriate hip products/systems to be used after breakage of a ceramic hip component as indicated in the ceramic hip component instructions for use.

Ceramic hip systems have been used in total hip arthroplasty for many years. However, in some cases and due to various factors, revision surgery may be required due to ceramic component breakage.

In these cases of revision, all the ceramic particles must be removed and the wound thoroughly irrigated. The broken ceramic component should be replaced with another ceramic component, resulting in a "ceramic on ceramic" or "ceramic on polyethylene" articulation, according to the basic rule "once ceramic - always ceramic."

A ceramic/ceramic or ceramic/polyethylene combination must be used in case of a revision surgery due to breakage of a ceramic component.

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Risks

Because of the risk of ceramic particles remaining in the tissue, the use of metal heads for revision after breakage of ceramic components is not appropriate. Otherwise this could lead to:

- Pain, joint effusion, progressive or sudden decrease of mobility
- Foreign body reaction due to ceramic debris/ particles
- Necrosis, pseudo-tumor and aseptic loosening
- Revision surgery
- Premature tribological wear of the revision component due to abrasion caused by remaining particles of the revised ceramic components

Furthermore, a limited number of case reports in medical literature[1] have suggested the potential for systemic cobalt toxicity leading to severe complications, such as death.

Your Responsibilities

1. Review this notification and ensure affected team members are aware of the contents.
2. Inform your affected customers using the surgeon letter.
3. There are no specific patient monitoring instructions related to this Field Safety Notice that are recommended beyond your existing follow up schedule.
4. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy to fieldaction.eire@zimmerbiomet.com
    b. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your documentation.

Other Information

This medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

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

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

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[1] Fatal cobalt toxicity after total hip arthroplasty revision for fractured ceramic components: Kimberly A. Fox, Todd M. Phillips, Joseph H. Yanta, Michael G. Abesamis: 10.1080/15563650.2016.1214274 Published 4 August 2016

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We would like to thank you for your co-operation in advance and regret any inconveniences caused by this Field Safety Notice.

Sincerely,

Anne-Catherine Morancy Meister
Post Market Surveillance Manager

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ATTACHMENT 1
Certificate of Acknowledgement

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IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Territory Number: _____ **Account Number:** _____

Account Name: _____

Account Address: _____

Certificate of Acknowledgement:

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

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** ( ) ____-_____ x _____ **Date:** ___/___/_____

Note: This form must be returned to Zimmer Biomet before this action can be considered closed for your account. It is important that you complete this form and email a copy to: fieldaction.eire@zimmerbiomet.com