



February 13, 2017

To: Hospitals and Surgeons

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 Surgeon,

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.

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 literature¹ have suggested the potential for systemic cobalt toxicity leading to severe complications, such as death.

Surgeon/ Clinic Responsibilities:

1. Review this Field Safety Notice immediately and ensure affected personnel are aware of the contents without delay.
2. Use Zimmer Biomet hip systems according to this Field Safety Notice.
3. Complete the Certificate of Acknowledgement (Attachment 1) to confirm the receipt of this Field Safety Notice and
 - a. Return a digital copy to fieldaction.emea@zimmerbiomet.com or to your local Zimmer Biomet contact.
 - b. Retain a copy of the Certificate of Acknowledgement with your records in the event of a compliance audit of your facilities documentation.
4. If after reviewing this Field Safety Notice you have further questions or concerns, please contact your Zimmer Biomet sales representative.

Other Information

This Medical Devices 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 winterthur.per@zimmerbiomet.com or your local Zimmer Biomet contact.

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

¹

[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



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

Sincerely,

A handwritten signature in blue ink, appearing to read 'Anne-Catherine Morancy Meister', written over a horizontal line.

Anne-Catherine Morancy Meister
Post Market Surveillance Manager

Attachment 1 Certificate of Acknowledgement

FSN/FSCA: FA 2016-10 (ZFA2016-150)

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.

Please email or fax the completed form to fieldaction.emea@zimmerbiomet.com or to your local Zimmer Biomet contact:

Fax / Email _____ / _____

By signing below, I acknowledge that I have received and understand the content of the Urgent Field Safety Notice.

Printed Name: _____

Signature: _____

Hospital Name: _____

Hospital Address: _____

Phone Number: _____

Please maintain a copy of your completed form with your internal records.