ZIMMER BIOMET

May 18, 2016

To: **Hospitals and Surgeons**

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

FSN/FSCA: **FA 2016-04**

Affected Product: **Zimmer Biomet / Anatomical Shoulder 2.0 Dome Centric**

Material Number: 01.04227.005 & Selected lot numbers

Dear Sirs,

Zimmer GmbH is initiating a voluntary removal of the Dome Centric component (Reference 01.04227.005) from the Anatomical Shoulder (AS) System 2.0 that may be in your inventories. Please see attachment 1 for the involved lot numbers.

The Dome Centric connects the Humeral Stem to the Humeral Head and allows setting an inclination and retroversion positioning. The Dome Centric component for the AS System 2.0 was launched in the 2015 into the EMEA market and in the 2016 In the US Market.

Picture 1: View of the new edition of the Dome Centric component for AS System 2.0

During monitoring of the products a potential risk was recently identified. Indeed during the use of the newly launched version of the Dome Centric in connection with the raps instrument, it was observed that it might be difficult to disassemble the Dome Centric from the rasp if the expansion ball would fully seat in the rasp. In all the reported cases (6 complaints were registered), the surgery was successfully completed.

Our records indicate that you may have received one or more of the affected products.

Risks
The removal of the Dome Centric is based on the following possible risks due to the potential difficult disassembly between the Dome Centric and the rasp.

1) If the surgeon would not be able to disassemble the Dome Centric from the AS Humeral Rasp, the surgeon must then use a second Dome Centric or an alternative device, from inventories and this could conduct to a slight prolongation of the surgery to get a new device.
2) If the surgeon would not be able to disassemble the Dome Centric from the AS Humeral Rasp, and if the surgeon would decide not to use any alternative product, he/she would

have the option to further proceed with the surgery disassembling the Dome centric from the humeral rasp ex-situ, impacting on the neck of the proximal part of the rasp. Before impacting, the surgeon should take note of the head orientation of the laser mark on the dome. This could potentially result in a delay of surgery time of more than 30min.

3) The Dome Centric could sink down while compressing the resected humeral area in patients with lower bone quality.

4) If the surgeon would not be able to align the head orientation of the Dome to the trial head by using the laser marking, the surgeon might decide to close the wound without finishing the surgery and schedule a different therapeutic approach at a later stage.

No complaints have been reported alleging the scenario 3 and 4.

Your Responsibilities

1. Review the notification immediately and ensure affected personnel are aware of the contents without delay.
2. Assist your Zimmer Biomet sales representative with the quarantine of any device mentioned in attachment 1.
3. Your Zimmer Biomet sales representative will remove the affected device, if any, from your facility.
4. Complete the Certification of Acknowledgement from (Attachment 2) and return to fieldaction.emea@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**
6. **Caution:** After the removal of the affected products, the delivery of the Dome Centric will be interrupted during certain time. In case of a potential revision surgery of an already implanted product, please immediately contact your Zimmer Biomet sales representative for more information.

Vigilance/ Reporting Information

This voluntary notification will be reported to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 or any relevant requirements to the local health authority in your country.

Please keep Zimmer GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

Kind regards,

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Anne-Catherine Morancy Meister
PMS Manager

ZIMMER BIOMET

Attachment 1

Product Scope – Affected batch Numbers

Material Number	Batch
01.04227.005	2775008
01.04227.005	2777491
01.04227.005	2792457
01.04227.005	2794576
01.04227.005	2794577
01.04227.005	2794578
01.04227.005	2794579
01.04227.005	2794580
01.04227.005	2812029
01.04227.005	2815118
01.04227.005	2815119
01.04227.005	2817212
01.04227.005	2817213
01.04227.005	2817214
01.04227.005	2831247
01.04227.005	2832862
01.04227.005	2834002
01.04227.005	2844463
01.04227.005	2847568
01.04227.005	2847569
01.04227.005	2847570

Attachment 2
Certificate of Acknowledgement

FSN/FSCA: FA 2016-04

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Material Number: 01.04227.005 & Selected lot numbers

Please email or fax the completed form 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 – Removal, and that the required actions have been taken in accordance with the notice:

1. Return parts in inventory
2. Fill the list below
3. Sign the form

Product reference	Quantity to return

☐ All parts received were implanted.

Printed Name:_____

Signature:_____

Hospital Name: _____

Hospital Address:_____

Phone Number:_____

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