ZIMMER BIOMET

March 01, 2018

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: M/L Taper Femoral Stem

Item Number	Item Description	Lot Number
00-7711-007-40	Femoral Stem 12/14 Neck Taper Plasma Sprayed Press-Fit Cementless Size 7.5 Extended Offset Reduced Neck Length	63716611
00-7711-004-10	Femoral Stem 12/14 Neck Taper Plasma Sprayed Press-Fit Cementless Size 4 Standard Reduced Neck Length	63716613
00-7711-004-10	Femoral Stem 12/14 Neck Taper Plasma Sprayed Press-Fit Cementless Size 4 Standard Reduced Neck Length	63716614

Zimmer Biomet is conducting a medical device recall for three lots of M/L Taper Femoral Stems noted in the table above. Following the receipt of two complaints, an investigation determined that certain packages labeled to contain the size 7.5 Extended Offset Reduced Neck length, actually contained a Size 4 Standard Reduced Neck length taper. Accordingly, all three lots that were determined to be potentially commingled are being recalled from the field.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Surgeon recognizes issue prior to implantation, surgery delay less than 30 minutes.	Surgery delay greater than 30 minutes for a product that is not readily available.
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	N/A	N/A

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between August 2017 and October 2017.

Risk Manager Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing Zimmer.PER@zimmerbiomet.com.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

[redacted]

Kevin W. Escapule
Post Market Surveillance and Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: M/L Taper Femoral Stem Field Action Reference: ZFA 2018-00046

Please check one as applicable:

☐ Hospital Facility

Do you have affected product in your facility?
(Hospital Facility Only: Please mark the appropriate response.)

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date:**____/____/____

Facility Name: _____

Facility Address: _____

City:_____ **State:**_____ **ZIP:**_____

Note: This form must be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com or fax to **574-372-4265**.