ZIMMER BIOMET

January 03, 2018

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL – Lot Specific**

Affected Product: Trabecular Metal Stems

Item Number	Lot Number	Device description
00-7864-013-00	63703649	TM Stem 13mm Standard
00-7864-013-20	63703681	TM Stem 13mm Extended

Zimmer Biomet is conducting a medical device recall for two lots of Trabecular Metal Stems noted in the table above. A complaint was received indicating that a “13mm Extended” stem was in a box labelled as a “13mm standard” stem. The investigation determined that the lots were commingled; hence both the lots 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
	Delay of Surgery less than 30 minutes.	Delay of Surgery greater than 30 minutes.
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	None

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

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Trabecular Metal Stems **Field Action Reference: 2017-499**

Do you have affected product in your facility?

☐ **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.