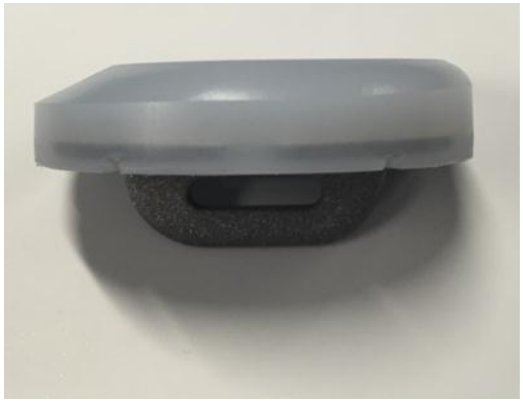
December 9, 2016

To: Risk Managers

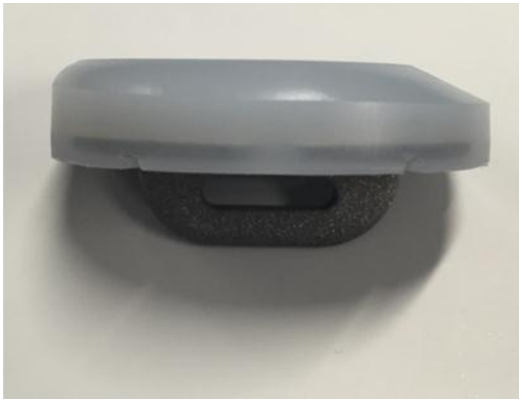
Subject: **URGENT MEDICAL DEVICE RECALL –LOT SPECIFIC**

Affected Product:

Oxford Fixed Lateral Bearing Size F Right, Part Number 154375 Lot 744260



Left



Right

Zimmer Biomet is initiating a removal of a single lot of Oxford Fixed Lateral Bearings that may be in your inventory. Zimmer Biomet received two product complaints reporting that when the package labeled as a “Right” was opened it actually contained a “Left” Bearing.

Risks: If another bearing is not available, a delay greater than 30 minutes may occur. If the product of the incorrect orientation is implanted, premature revision may be required.

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

Risk Manager Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. Your Zimmer Biomet sales representative will remove the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
    a. Return a digital copy within three (3) days via email to corporatequality.postmarket@zimmerbiomet.com.

5. If after reviewing this notice you have further questions or concerns please call 1-877-946-2761 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of business hours will receive a prompt to record a voicemail and will be returned upon receipt. Alternatively, your questions may be sent by email to corporatequality.postmarket@zimmerbiomet.com

Other Information

This voluntary 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.

- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch 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 even. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing product.experience@zimmerbiomet.com

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

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

Sincerely,

[redacted]

ATTACHMENT 1
Certificate of Acknowledgement

By signing below, I acknowledge that the required actions have been taken in accordance with the Recall Notice.

[ ] **Hospital Facility**

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 can be considered closed for your account. It is important that you complete this form and send a copy via email to corporatequality.postmarket@zimmerbiomet.com, in addition to including a copy with your product returns.