ZIMMER BIOMET

January 11, 2016

To: **Risk Managers**

Subject: **URGENT MEDICAL DEVICE RECALL**

A list of affected product is located at:

URL	User ID	Password
aplist1.zimmerbiomet.com	ap01	Today123

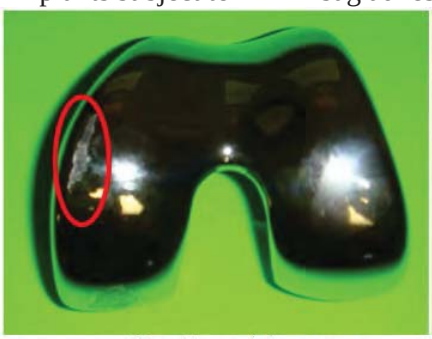
You are receiving this letter because our records indicate that you have or may have received a subset of highly polished implants, that were packaged in a low density polyethylene (LDPE) bag with a potential to adhere to the implants.

This notification is a follow up to the correction notice provided in August 2013. At that time and after a thorough investigation into the cause of the issue, Zimmer Biomet implemented a change to package the highly polished implants with a new LDPE bag. Testing has shown that this new bag resolves the issue and prevents the bag from adhering to the implants. Nonetheless, Zimmer Biomet has continued to receive complaints that the old LDPE bag containing the implant adheres to the highly polished implant surface. The frequency of this occurrence is approximately 1 in 12,800 cases. Accordingly Zimmer Biomet is removing the affected product remaining in the field.

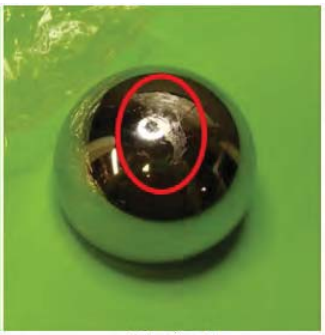
Zimmer Biomet has performed an extensive evaluation of the potential risks associated with this type of event and has concluded that it is unlikely that adhesion of the LDPE bag would cause an adverse effect to either the patient or function of the implant. This conclusion was based on the following:

- The LDPE material is biocompatible, similar to ultra high molecular weight polyethylene (UHMWPE).
- LDPE is softer than the two mating materials of UHMWPE and cobalt chrome molybdenum (CoCrMo). Therefore, is not expected to scratch either wear surface, which could increase wear rates and possibly lead to osteolysis.
- If there were wear particulates generated from the adhered film/residue of a LDPE bag they would be expected to elicit similar biologic reactions as those from UHMWPE and are unlikely to increase the likelihood of peri-prosthetic osteolysis.

Representative pictures of implants subject to LDPE bag adhesion, are shown below.



Knee Femoral Component



Bipolar Cup

CPT® Stem

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	• Device is packaged with LDPE bag exhibiting the issue; • Conditions are such that the LDPE bag adheres to the device; • OR staff recognizes that the LDPE bag has stuck to the device; • Extended surgery time of less than 10 minutes to locate another device of the same size or up size/down size depending on the patient.	• Device is packaged with LDPE bag exhibiting the issue; • Conditions are such that the LDPE bag adheres to the device; • OR staff recognizes that the LDPE bag has stuck to the device; • Another suitable device is not readily available; • Delay in surgery greater than 30 minutes to locate another device or to prepare for a different implant.
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	No long range health consequences are expected.	No long range health consequences are expected.

Your Responsibilities

1. Review the notification and ensure that relevant personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative with the quarantine of any affected product.
3. Your Zimmer Biomet sales representative will remove the recalled product from your facility.
4. Complete and return the attached Certificate of Acknowledgment form to corporatequality.postmarket@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please call customer service at 1-800-348-2759 or contact your Zimmer Biomet Sales Representative.**

Other Information

This voluntary recall was reported to the U.S. Food and Drug Administration.

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 regular mail or by fax.

- Online:www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at zimmer.per@zimmerbiomet.com.

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ATTACHMENT 1

Certificate of Acknowledgement:

A list of affected product is located at:

URL	User ID	Password
aplist1.zimmerbiomet.com	ap01	Today123

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

Printed Name: _____ Signature: _____

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

Facility Name: _____

Facility Address: _____

City: _____ State: _____ ZIP: _____

Note: This form and affected product must be returned to Zimmer Biomet before this action can be considered closed for your account. It is your responsibility to complete this form and email a copy to: CorporateQuality.PostMarket@ZimmerBiomet.com, in addition to including a copy with your product returns. Clearly mark the outside carton of each product return shipment made as "Recall." Please keep a copy of your completed form for your records.

Please do not return recalled product with other returns.

ZFA 2015-180