ZIMMER BIOMET

January XX, 2016

To: **Distributors, Sales Representatives, and Territory Operation Managers**

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

FSN/FSCA title: **Several Hip, Knee and Shoulder products with a high polished surface packaged in LDPE (Low Density Polyethylene) pouches**

A list of affected product is located at:

URL	User ID	Password
aplist3.zimmerbiomet.com	ap03	WTR2016

You are receiving this letter because our records indicate that you currently distribute a subset of highly polished implants, 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) and 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. If you find any affected product from the lists in your possession or at hospital accounts, quarantine the product immediately.
3. Return any affected inventory within your possession and from hospital accounts within your territory. Clearly mark the outside of all return packages, "RECALL," and include a copy of the Inventory Return Certification Form (Attachment 1) with a spreadsheet that includes item number, lot number, and quantity of all returns along with your return shipment(s). Additionally, email a copy of Attachment 1 and the spreadsheet identifying your returns to fieldaction.emea@zimmerbiomet.com. All inventory and documentation returns are expected to be complete within 4 weeks (February 19, 2016).
4. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**

Vigilance 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 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.

ATTACHMENT 1

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Inventory Return Certification Form
Ref.1: 1822565-12-22-2015-014-R
Ref.2: FA 2016-01

Territory Number: _____ Account Number: _____

Account Name: _____Phone Number: ( ) _____-_____

Account Address: _____

Please immediately return the affected product to the following address with a spreadsheet containing item number, lot number, and quantity:

Zimmer Biomet International Logistics GmbH
Attn: Tim Nowak (Recall Warsaw)
Max-Immelmann-Allee 12
79427 Eschbach Germany

_____Credit My Account OR _____Send a Replacement

Select one of the following with regard to locating and returning the affected product in your territory:
□ An exhaustive search has been conducted and all affected products have been returned – see attached spreadsheet itemizing the returned product. Units not returned are no longer available in inventory and considered as consumed.
□ Further attempts are being made to locate additional affected products returned – see attached spreadsheet with itemization of product being returned at this time. Additional returns may follow.

Note: A final Inventory Certification Form will need to be received from your territory confirming that all affected units have been returned from the territory and from direct and consigned inventories at hospital accounts. Be certain to return a copy of this form along with your return shipments and mark the outside of the return cartons as "RECALLED PRODUCT."

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

Printed
Name:_____Signature:_____

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

Note: This form and affected product must be returned to Zimmer Biomet before this action can be considered closed for your account. Please complete this form and email a copy to: fieldacion.emea@zimmerbiomet.com. Please keep a copy of this form with your records in the event of an audit concerning this recall.

Please do not return recalled product with other returns.

ZFA 2015-180