

March 17, 2016

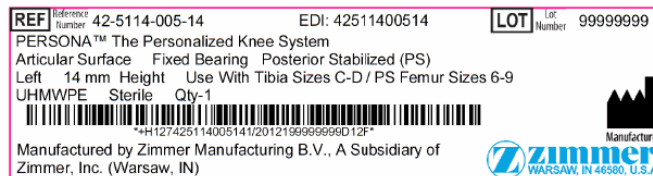
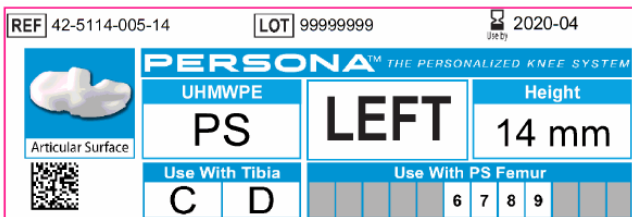
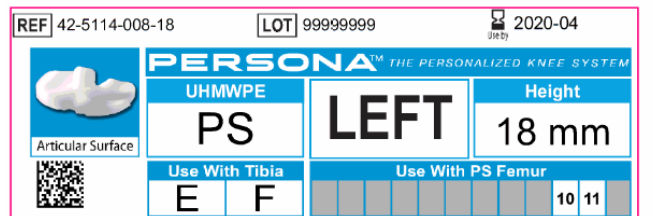
To: **Hospital Risk Manager**

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

Affected Product: **Persona PS Articular Surfaces**

Item No.	Lot(s) No.
42511400818	62632101
42511400514	62646580

Zimmer Inc. is initiating a lot specific recall of the Persona PS Articular Surfaces due to a label commingling issue between lots 62632101 and 62646580 and the potential consequences associated with this failure. The individual product box features two different product information labels on two different sides. These products were distributed in the United States, Asia Pacific, and Europe/Middle East/Africa, between April 2014 and January 2016.



Example of Product labels for the affected products

Risk

- A delay in surgery of up to 30 minutes while a replacement device is found could occur.

Your Responsibilities

1. Review the notification and ensure all affected 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 the Certificate of Acknowledgement Form (Attachment 1) and return to corporatequality.postmarket@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please call the customer call center at 1-800-348-2759 between 8:00 am and 8:00 pm EST.**

Other Information

This 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.

ATTACHMENT 1

Certificate of Acknowledgement:

Affected Product:

Persona PS Articular Surfaces

Item No.	Lot(s) No.
42511400818	62632101
42511400514	62646580

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 2016-36