


June 22, 2017

To: Surgeons/ Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (LABELING CHANGE)**

Affected Product: Comprehensive Nano Humeral Components | Reverse Configuration

Zimmer Biomet is conducting a medical device field action for the following Comprehensive Nano Humeral Components in order to perform a labeling update:

Item No.	Description	Size	Component Picture
115730	Comprehensive Nano Humeral Component PPS	30mm	
115732	Comprehensive Nano Humeral Component PPS	32mm	
115734	Comprehensive Nano Humeral Component PPS	34mm	
115736	Comprehensive Nano Humeral Component PPS	36mm	
115738	Comprehensive Nano Humeral Component PPS	38mm	
115740	Comprehensive Nano Humeral Component PPS	40mm	

Prior to this notice, the Comprehensive Nano Humeral Component could be used in the anatomic or reverse configuration; however, data collected during an annual post market surveillance review, in addition to clinical study data, has indicated that the Comprehensive Nano Humeral Component did not meet the expected performance rate (EPR) when used **in the reverse configuration**. Specifically, the clinical study data documents 5 revision surgeries out of a total of 44 implanted components in the reverse configuration. Therefore, the Comprehensive Nano Humeral Component must no longer be used in the reverse configuration.

Due to the Comprehensive Nano Humeral Component exceeding the EPR when used in the reverse configuration, Zimmer Biomet is performing a labeling correction for the affected components to update the Instructions for Use included with the implant to remove the indication for the reverse configuration. The indication for the anatomic configuration will remain unchanged.

The failure to meet the EPR **only** relates to the reverse configuration. For the anatomic configuration, the post market review data indicates that the device is performing better than the EPR; therefore, **the Comprehensive Nano Humeral Component may still be used in the anatomic configuration while the instructions for use are being updated.**

Usage of the affected Comprehensive Nano Humeral Components in the reverse configuration should cease immediately.

There are no immediate health consequences, and the highest severity long-range health consequence that may result is revision due to loosening.

Our records indicate that you may have received one or more of the affected products, which were distributed between the August 2012 and April 2017.

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. Immediately stop using the affected items in the reverse configuration; usage in the anatomic configuration is permitted in accordance with the current Instructions for Use.
3. Once inventory is available with the updated Instructions for Use, your Zimmer Biomet sales representative **will replace any remaining affected product in your facility with product that has been corrected to include the updated Instructions for Use.**
4. Complete the attached Certificate of Acknowledgment (**Attachment 1**).
 - a. **To ensure the replacement, please list number of products in your inventories**
 - b. Return a digital copy to fieldaction.emea@zimmerbiomet.com.
 - c. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit.
5. If you have further questions or concerns after reviewing this notice, please contact your local Zimmer Biomet sales representative.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. Immediately stop using the affected items in the reverse configuration; usage in the anatomic configuration is permitted in accordance with the current Instructions for Use.
3. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow up schedule.
4. Complete Attachment 1 – Certificate of Acknowledgement.
 - a. Return a digital copy to fieldaction.emea@zimmerbiomet.com
 - b. Retain a copy of the Acknowledgement Form with your field action records in the event of a compliance audit of your documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your local Zimmer Biomet sales representative.

Other Information

This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@zimmerbiomet.com or to your local Zimmer Biomet contact.

The undersigned confirms that this notice has been delivered to the appropriate Competent Authorities, as per MEDDEV 2.12-1 revision 8.

We would like to thank you for your cooperation in advance and regret any inconveniences caused by this field action.

Sincerely,

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ATTACHMENT 1
Certificate of Acknowledgement- ZFA 2017-166

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

Hospital Facility Surgeon (Please check one as applicable)

Printed Name: _____ Signature: _____

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

Facility Name: _____

Facility Address: _____

City: _____ ZIP: _____ Country: _____

Note: This form must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to: fieldaction.emea@zimmerbiomet.com

Please indicate the quantity of products in your inventories

Product Reference	Lot Reference	Number of products in your inventory