ZIMMER BIOMET

FACILITY NAME

June 16, 2017

To: Surgeons, clinics, hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE REMOVAL**

Affected Product: Various Trauma, Extremities, Hips and Knees Implants

Item Number	Lot Number	Product Segment	Product Description
350837	340530	Trauma	LATERAL TROCH PLATE FULL CRIMP – 254 mm
350838	406590	Trauma	LATERAL TROCH PLATE SHORT CRIMP – 159 mm
11-113562	529890	Extremities	COMP 12MM HUM FRAC STEM MACRO
113628	523080	Extremities	COMP PRIMARY STEM 8MM MINI
192009	410150	Hips	ECHO POR FMRL NC 9X125
650-1064	854540	Hips	CER OPTION TYPE 1 TPR SLEVE -6
650-1056	843260	Hips	CER BIOLOXD OPTION HD 32MM
150366	71180	OSS Knees	OSS CEMENTED IM STEM 12X150
CP111817	856460	PMI Knees	RED SEXP DSTL FEM 19CM RT ASSY
CP111828	856550	PMI Knees	RED SEXP DSTL FEM 19CM LT ASSY

Zimmer Biomet is conducting a medical device field action for various Trauma, Extremities, Hips and Knees implants. There is a possibility that the patient label inside the product box was incorrectly labeled. The outer box label and the actual product are correct, but the internal patient label could potentially be incorrect.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	None, issue description is compliance related.	*None, issue description is compliance related.*
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	*Most Probable*	*Worst Case*
	None, issue description is compliance related.	*None, issue description is compliance related.*

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of November 2009 and April 2017.

Hospital/ Surgeon Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative to quarantine all affected product.
3. Your Zimmer Biomet sales representative will support you for the removal of the affected product from your facility.

4. Check if any identified products were already used and confirm that the patient labels in your records are correct. Refer/ use to the table below for the information regarding the products implanted at your facility. This list is for your own records checking.

Item Number	Lot Number	Item Description	Surgery Date	Surgeon Name	Patient Identifier

5. 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 facilities documentation.
6. If after reviewing this notice you have further questions or concerns please your Zimmer Biomet 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.

……
……..

ATTACHMENT 1
Certificate of Acknowledgement- ZFA 2017-167

Affected Product: Various Trauma, Extremities, Hips and Knees Implants

By signing below, I acknowledge that the required actions have been taken in accordance with the 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 can be considered closed for your account. It is important that you complete this form send a copy to fieldaction.emea@zimmerbiomet.com .

Please confirm the following:

I herewith confirm that for the products already implanted, the patient records were checked and corrected where applicable.

or

None of the identified products were used.

Following identified products are being returned:

Product Reference	Lot Reference	Number of returned products