October 9, 2017

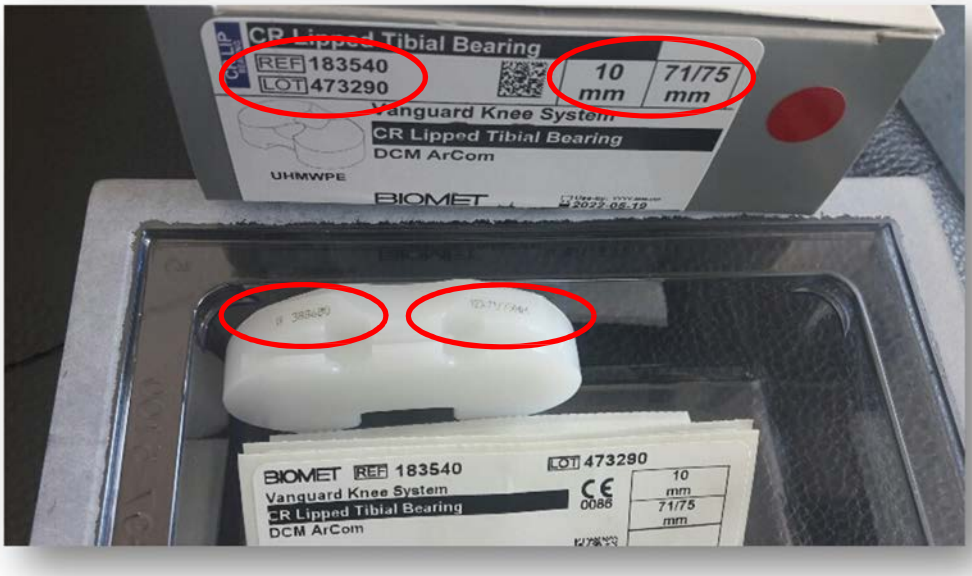
To: Surgeons/ Hospital

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

Affected Product: Vanguard CR Tibial Bearing and Vanguard CR Lipped Tibial Bearing

Item Number	Lot Number	UDI Number
183540	473290	(01)00880304271531(17)220519(10)473290
183442	388680	(01)00880304271142(17)220519(10)388680

Zimmer Biomet is conducting a medical device field action (removal) for the Vanguard CR Tibial Bearing and the Vanguard CR Lipped Tibial Bearing. Product complaints indicate that the lots were comingled; specifically, the part listed on the label differed from the physical product inside the packaging. The mislabeled product is detected by comparing the label on the packaging to the laser etched size on the device. Should the mislabeled device be implanted, the most probable and highest severity consequence is a delay of surgery less than 30 minutes. There are no probable long-range health consequences; the highest severity long-range health consequence is poor joint mechanics potentially leading to revision.



Our records indicate that you may have received one or more of the affected products. The affected units were distributed from June to July, 2017.

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will support the removal of the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet sales representative.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow-up schedule; however, the issue associated with this field action should be considered if a patient received an affected device and presents with stiffness or instability.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.netherlands@zimmerbiomet.com.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
6. If you have further questions or concerns after reviewing this notice, please contact your 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 as per MEDDEV 2.12-1 in Europe.

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

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

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

Sincerely,

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ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Vanguard Tibial Bearings **Field Action Reference: ZFA 2017-358**

Please check one as applicable:

☐ Hospital Facility ☐ Surgeon

Do you have affected product in your facility?
(Hospital Facility Only: Please mark the appropriate response.)

☐ **Yes**, we currently have one or more affected items in our facility.

☐ **No**, we currently have no affected items in our facility.

Product Reference	Lot Reference	Number of products returned

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

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 closed for your account. It is important that you complete this form and email a copy to fieldaction.netherlands@zimmerbiomet.com