

September 29, 2017

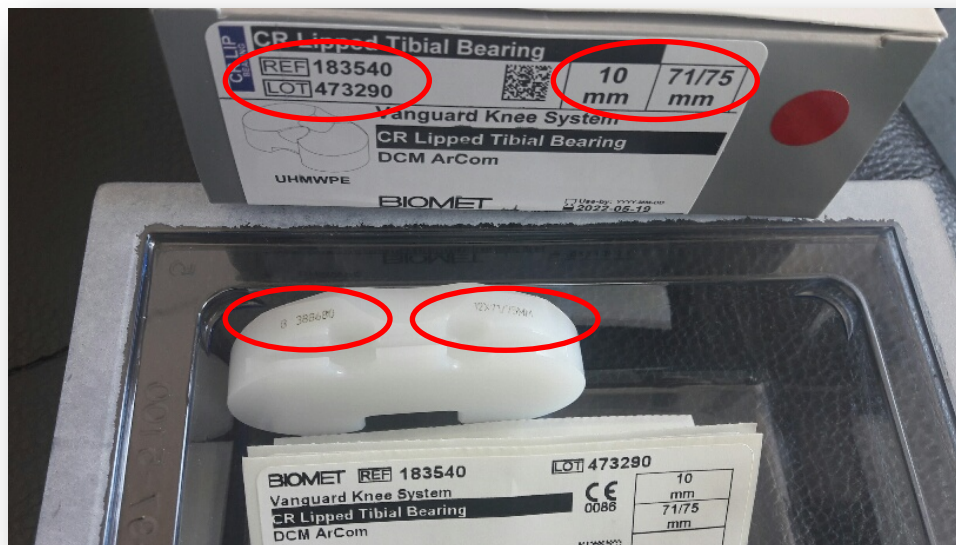
**To:** Risk Managers and Surgeons

**Subject:** **URGENT MEDICAL DEVICE RECALL (REMOVAL)**

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

Description	Item #	Lot #	UDI Number
Vanguard CR Lipped Tibial Bearing	183540	473290	(01)00880304271531(17)220519(10)473290
Vanguard CR Tibial Bearing	183442	388680	(01)00880304271142(17)220519(10)388680

Zimmer Biomet is conducting a medical device recall 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.

**Risk Manager 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 remove the affected product from your facility.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@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 recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com).

**Surgeon Responsibilities:**

1. Review this notification for awareness of the contents.
2. There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule; however, the issue associated with this recall 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 [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com).
4. Retain a copy of the acknowledgement form with your recall 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 call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com).



### Other Information

This medical device recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are also required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing [product.experience@zimmerbiomet.com](mailto:product.experience@zimmerbiomet.com).

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.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

A redacted signature and name, consisting of a blacked-out area with a white rectangular cutout in the middle.



**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.

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

**Printed Name:** \_\_\_\_\_ **Signature:** \_\_\_\_\_

**Title:** \_\_\_\_\_ **Telephone:** (    ) \_\_\_\_\_ - \_\_\_\_\_ **Date:** \_\_\_\_/\_\_\_\_/\_\_\_\_

**Facility Name:** \_\_\_\_\_

**Facility Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **ZIP:** \_\_\_\_\_

**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 [CorporateQuality.PostMarket@zimmerbiomet.com](mailto:CorporateQuality.PostMarket@zimmerbiomet.com) or fax to 574-372-4265.