

October 23, 2018

**To:** Risk Managers  
**Cc:** Chairman of Medical Board and all relevant Head(s) of Department  
**Subject:** **URGENT MEDICAL DEVICE RECALL**

**Affected Product: Vanguard PS Open Box Femorals**

Item Number	Lot Number	Description	UDI Number
183126	J6255863	PS Open Box Femoral – Left, 62.5 mm	(01)00880304270794(17)280411(10)J6265594
183108	J6265594	PS Open Box Femoral – Right, 65 mm	(01)00880304270893(17)280411(10)J6255863

Zimmer Biomet is conducting a lot specific medical device recall for the following Vanguard Knee System parts due to a potential packaging commingle: PS Open Box Femoral – Left, 62.5mm and PS Open Box Femoral – Right, 65mm. A complaint was reported that the label on the outer carton or the patient labels did not match with the label on the inner sterile packaging.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>Delay of surgery less than 30 minutes to find a replacement part</i>	<i>Delay of surgery greater than 30 minutes if replacement part is not readily available</i>
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	<i>None</i>	<i>None</i>

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between 05/02/2018 and 09/05/2018.

**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).

### 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).

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

Sincerely,



Kevin W. Escapule  
Post Market Surveillance and Regulatory Compliance Director



**ATTACHMENT 1**  
**Certificate of Acknowledgement**

**IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED**

**Affected Product: Vanguard PS Open Box Femorals**

**Field Action Reference: 2018-00484**

<p><b>Do you have affected product in your facility?</b></p> <p><input type="checkbox"/> <b>Yes</b>, we currently have one or more affected items in our facility.</p> <p><input type="checkbox"/> <b>No</b>, we currently have no affected items in our facility.</p>
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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.