

30<sup>th</sup> August 2017

**To:** Surgeons/ Hospital

**Subject:** **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE REMOVAL – LOT SPECIFIC**

**Affected Product: Vanguard Open Box Posterior Stabilized Femoral Components**

Refer to **Attachment 2 – Affected Product List** for the affected items/lot combinations.



Zimmer Biomet is conducting a lot specific medical device field safety notice for Vanguard Open Box Posterior Stabilized Femoral components due to inadequate line clearance at the supplier between April 5, 2016 and September 1, 2016. As a result, the packaging of some femoral components was incorrectly labeled as either smaller or larger and/or as the incorrect side (right/left). It is highly detectable at the point of use that the device was incorrectly labelled. The estimated rate of occurrence is <1 in 1,000 products.

The incorrectly labeled products could have the potential risks as described below:

<i>Risks</i>		
<i>Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	<i>Most Probable</i>	<i>Worst Case</i>
	<i>Delay in surgery less than 30 minutes</i>	<i>Revision of knee</i>
<i>Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.</i>	<i>Most Probable</i>	<i>Worst Case</i>
	<i>None</i>	<i>Revision of knee</i>

Our records indicate you may have received one or more of the affected products. The affected units were distributed between the dates of April 2016 and June 2017.

**Surgeon/ Hospital Responsibilities:**

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative with quarantine of all affected product.
3. Your Zimmer Biomet sales representative will support you for the removal the affected product from your facility.
4. Complete **Attachment 1 – Certificate of Acknowledgement**.
  - a. Return a digital copy to [fieldaction.netherlands@zimmerbiomet.com](mailto:fieldaction.netherlands@zimmerbiomet.com)
  - b. Retain a copy of the Acknowledgement Form with your recall records in the event of a compliance audit of your facilities documentation.
5. If after reviewing this notice you have further questions or concerns please contact 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 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](mailto: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.

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 recall.

Sincerely,

---

...  
...



**ATTACHMENT 1**  
**Certificate of Acknowledgement (ZFA 2017-274)**

**Affected Product: Vanguard Open Box Posterior Stabilized Femoral Components**

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

Hospital Facility       Surgeon

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 can be considered closed for your account. It is important that you complete this form and return a copy to [fieldaction.netherlands@zimmerbiomet.com](mailto:fieldaction.netherlands@zimmerbiomet.com)**

Product Reference	Lot Reference	Number of products returned

**ATTACHMENT 2 - Affected Product List**

ITEM	LOT	ITEM DESCRIPTION	ITEM	LOT	ITEM DESCRIPTION
183100	J3762503	VNGD PS OPEN INTL FEM RT 55	183113	J3775066	VAN PS OPEN INTL FEM-RT 72.5
183100	J3848990	VNGD PS OPEN INTL FEM RT 55	183113	J3808188	VAN PS OPEN INTL FEM-RT 72.5
183102	J3823508	VNGD PS OPEN INTL FEM-RT 57.5	183113	J3844351	VAN PS OPEN INTL FEM-RT 72.5
183102	J3844280	VNGD PS OPEN INTL FEM-RT 57.5	183120	J3759784	VAN PS OPEN INTL FEM-LT 55
183104	J3757670	VNGD PS OPEN INTL FEM RT 60	183120	J3778481	VAN PS OPEN INTL FEM-LT 55
183104	J3786139	VNGD PS OPEN INTL FEM RT 60	183120	J3823823	VAN PS OPEN INTL FEM-LT 55
183104	J3791599	VNGD PS OPEN INTL FEM RT 60	183120	J3830028	VAN PS OPEN INTL FEM-LT 55
183104	J3802691	VNGD PS OPEN INTL FEM RT 60	183120	J3844303	VAN PS OPEN INTL FEM-LT 55
183104	J3802695	VNGD PS OPEN INTL FEM RT 60	183122	J3772636	VAN PS OPEN INTL FEM-LT 57.5
183104	J3810093	VNGD PS OPEN INTL FEM RT 60	183122	J3778392	VAN PS OPEN INTL FEM-LT 57.5
183104	J3834879	VNGD PS OPEN INTL FEM RT 60	183122	J3795040	VAN PS OPEN INTL FEM-LT 57.5
183106	J3758452	VAN PS OPEN INTL FEM-RT 62.5	183122	J3808178	VAN PS OPEN INTL FEM-LT 57.5
183106	J3768944	VAN PS OPEN INTL FEM-RT 62.5	183122	J3844293	VAN PS OPEN INTL FEM-LT 57.5
183106	J3757656	VAN PS OPEN INTL FEM-RT 62.5	183124	J3759761	VAN PS OPEN INTL FEM-LT 60
183106	J3764277	VAN PS OPEN INTL FEM-RT 62.5	183124	J3759764	VAN PS OPEN INTL FEM-LT 60
183106	J3772644	VAN PS OPEN INTL FEM-RT 62.5	183124	J3764400	VAN PS OPEN INTL FEM-LT 60
183106	J3779238	VAN PS OPEN INTL FEM-RT 62.5	183124	J3783522	VAN PS OPEN INTL FEM-LT 60
183106	J3789448	VAN PS OPEN INTL FEM-RT 62.5	183124	J3779297	VAN PS OPEN INTL FEM-LT 60
183106	J3787579	VAN PS OPEN INTL FEM-RT 62.5	183124	J3789079	VAN PS OPEN INTL FEM-LT 60
183106	J3801874	VAN PS OPEN INTL FEM-RT 62.5	183124	J3792553	VAN PS OPEN INTL FEM-LT 60
183106	J3810115	VAN PS OPEN INTL FEM-RT 62.5	183124	J3797409	VAN PS OPEN INTL FEM-LT 60
183106	J3802767	VAN PS OPEN INTL FEM-RT 62.5	183124	J3808164	VAN PS OPEN INTL FEM-LT 60
183106	J3806238	VAN PS OPEN INTL FEM-RT 62.5	183124	J3830639	VAN PS OPEN INTL FEM-LT 60
183106	J3806239	VAN PS OPEN INTL FEM-RT 62.5	183124	J3829951	VAN PS OPEN INTL FEM-LT 60
183106	J3812163	VAN PS OPEN INTL FEM-RT 62.5	183124	J3849034	VAN PS OPEN INTL FEM-LT 60
183106	J3807740	VAN PS OPEN INTL FEM-RT 62.5	183126	J3770477	VAN PS OPEN INTL FEM-LT 62.5
183106	J3818101	VAN PS OPEN INTL FEM-RT 62.5	183126	J3764287	VAN PS OPEN INTL FEM-LT 62.5
183106	J3825020	VAN PS OPEN INTL FEM-RT 62.5	183126	J3764311	VAN PS OPEN INTL FEM-LT 62.5
183106	J3842173	VAN PS OPEN INTL FEM-RT 62.5	183126	J3764288	VAN PS OPEN INTL FEM-LT 62.5
183106	J3844489	VAN PS OPEN INTL FEM-RT 62.5	183126	J3778370	VAN PS OPEN INTL FEM-LT 62.5
183106	J3844492	VAN PS OPEN INTL FEM-RT 62.5	183126	J3779268	VAN PS OPEN INTL FEM-LT 62.5
183106	J3844484	VAN PS OPEN INTL FEM-RT 62.5	183126	J3778369	VAN PS OPEN INTL FEM-LT 62.5
183106	J3847277	VAN PS OPEN INTL FEM-RT 62.5	183126	J3792576	VAN PS OPEN INTL FEM-LT 62.5
183106	J3857383	VAN PS OPEN INTL FEM-RT 62.5	183126	J3795020	VAN PS OPEN INTL FEM-LT 62.5
183106	J3854449	VAN PS OPEN INTL FEM-RT 62.5	183126	J3795002	VAN PS OPEN INTL FEM-LT 62.5
183108	J3757650	VAN PS OPEN INTL FEM-RT 65	183126	J3807370	VAN PS OPEN INTL FEM-LT 62.5
183108	J3757652	VAN PS OPEN INTL FEM-RT 65	183126	J3807373	VAN PS OPEN INTL FEM-LT 62.5
183108	J3772612	VAN PS OPEN INTL FEM-RT 65	183126	J3823815	VAN PS OPEN INTL FEM-LT 62.5
183108	J3773081	VAN PS OPEN INTL FEM-RT 65	183126	J3826891	VAN PS OPEN INTL FEM-LT 62.5
183108	J3773072	VAN PS OPEN INTL FEM-RT 65	183126	J3844474	VAN PS OPEN INTL FEM-LT 62.5
183108	J3773074	VAN PS OPEN INTL FEM-RT 65	183126	J3844471	VAN PS OPEN INTL FEM-LT 62.5

ITEM	LOT	ITEM DESCRIPTION	ITEM	LOT	ITEM DESCRIPTION
183108	J3778377	VAN PS OPEN INTL FEM-RT 65	183126	J3854486	VAN PS OPEN INTL FEM-LT 62.5
183108	J3778381	VAN PS OPEN INTL FEM-RT 65	183126	J3854420	VAN PS OPEN INTL FEM-LT 62.5
183108	J3786084	VAN PS OPEN INTL FEM-RT 65	183128	J3762522	VAN PS OPEN INTL FEM-LT 65
183108	J3779278	VAN PS OPEN INTL FEM-RT 65	183128	J3759823	VAN PS OPEN INTL FEM-LT 65
183108	J3789091	VAN PS OPEN INTL FEM-RT 65	183128	J3753330	VAN PS OPEN INTL FEM-LT 65
183108	J3788098	VAN PS OPEN INTL FEM-RT 65	183128	J3772682	VAN PS OPEN INTL FEM-LT 65
183108	J3788107	VAN PS OPEN INTL FEM-RT 65	183128	J3785380	VAN PS OPEN INTL FEM-LT 65
183108	J3789093	VAN PS OPEN INTL FEM-RT 65	183128	J3800683	VAN PS OPEN INTL FEM-LT 65
183108	J3797399	VAN PS OPEN INTL FEM-RT 65	183128	J3798251	VAN PS OPEN INTL FEM-LT 65
183108	J3801355	VAN PS OPEN INTL FEM-RT 65	183128	J3800686	VAN PS OPEN INTL FEM-LT 65
183108	J3802747	VAN PS OPEN INTL FEM-RT 65	183128	J3798224	VAN PS OPEN INTL FEM-LT 65
183108	J3801354	VAN PS OPEN INTL FEM-RT 65	183128	J3816061	VAN PS OPEN INTL FEM-LT 65
183108	J3802634	VAN PS OPEN INTL FEM-RT 65	183128	J3819267	VAN PS OPEN INTL FEM-LT 65
183108	J3806207	VAN PS OPEN INTL FEM-RT 65	183128	J3842125	VAN PS OPEN INTL FEM-LT 65
183108	J3802638	VAN PS OPEN INTL FEM-RT 65	183128	J3847218	VAN PS OPEN INTL FEM-LT 65
183108	J3816069	VAN PS OPEN INTL FEM-RT 65	183128	J3847223	VAN PS OPEN INTL FEM-LT 65
183108	J3830642	VAN PS OPEN INTL FEM-RT 65	183130	J3759900	VAN PS OPEN INTL FEM-LT 67.5
183108	J3833240	VAN PS OPEN INTL FEM-RT 65	183130	J3792543	VAN PS OPEN INTL FEM-LT 67.5
183108	J3840011	VAN PS OPEN INTL FEM-RT 65	183130	J3799064	VAN PS OPEN INTL FEM-LT 67.5
183110	J3778428	VAN PS OPEN INTL FEM-RT 67.5	183130	J3802625	VAN PS OPEN INTL FEM-LT 67.5
183110	J3797446	VAN PS OPEN INTL FEM-RT 67.5	183130	J3807779	VAN PS OPEN INTL FEM-LT 67.5
183110	J3801302	VAN PS OPEN INTL FEM-RT 67.5	183130	J3815895	VAN PS OPEN INTL FEM-LT 67.5
183110	J3808916	VAN PS OPEN INTL FEM-RT 67.5	183130	J3849129	VAN PS OPEN INTL FEM-LT 67.5
183110	J3804238	VAN PS OPEN INTL FEM-RT 67.5	183132	J3753266	VAN PS OPEN INTL FEM-LT 70
183110	J3802703	VAN PS OPEN INTL FEM-RT 67.5	183132	J3775091	VAN PS OPEN INTL FEM-LT 70
183110	J3802705	VAN PS OPEN INTL FEM-RT 67.5	183132	J3773162	VAN PS OPEN INTL FEM-LT 70
183110	J3794963	VAN PS OPEN INTL FEM-RT 67.5	183132	J3775088	VAN PS OPEN INTL FEM-LT 70
183110	J3844453	VAN PS OPEN INTL FEM-RT 67.5	183132	J3847283	VAN PS OPEN INTL FEM-LT 70
183112	J3759871	VNGD PS OPEN INTL FEM RT 70	183133	J3821119	VAN PS OPEN INTL FEM-LT 72.5
183113	J3764319	VAN PS OPEN INTL FEM-RT 72.5	183133	J3849085	VAN PS OPEN INTL FEM-LT 72.5
183113	J3775063	VAN PS OPEN INTL FEM-RT 72.5			