

December 28, 2016

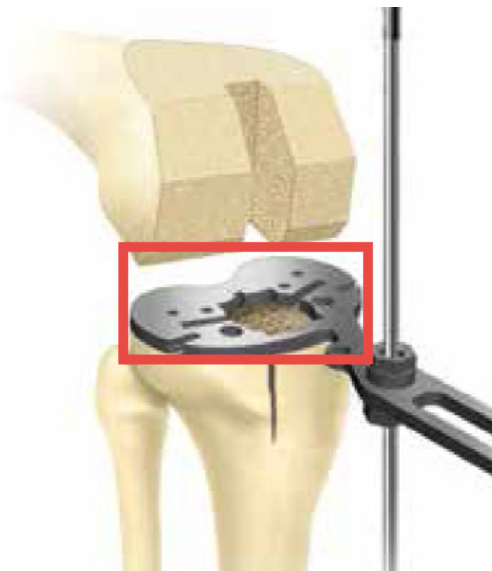
To: Risk Managers

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

Affected Product: Vanguard Knee Punch Thru Plates

Affected items are listed in the table below:

Description	Item	Lot
63MM PUNCH THRU TRL PLATE	32-487261	ZB160702
63MM PUNCH THRU TRL PLATE	32-487261	ZB160701
63MM PUNCH THRU TRL PLATE	32-487261	ZB160703
67MM PUNCH THRU TRL PLATE	32-487262	ZB160701
67MM PUNCH THRU TRL PLATE	32-487262	ZB160702
71MM PUNCH THRU TRL PLATE	32-487263	ZB160701
71MM PUNCH THRU TRL PLATE	32-487263	ZB160702
71MM PUNCH THRU TRL PLATE	32-487263	ZB160703
75MM PUNCH THRU TRL PLATE	32-487264	ZB160801
75MM PUNCH THRU TRL PLATE	32-487264	ZB160802
75MM PUNCH THRU TRL PLATE	32-487264	ZB160803
79MM PUNCH THRU TRL PLATE	32-487265	ZB160801
79MM PUNCH THRU TRL PLATE	32-487265	ZB160802





Zimmer Biomet is conducting a lot-specific medical device field action for specific lots of the Vanguard punch thru plates due to potential alumina inclusions in the raw material batch used to produce the affected products. Inclusions contained within the finished product could lead to the cracking and separation of the instrument.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	No immediate health consequences expected	No immediate health consequences expected
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Worst Case
	No long range health consequences expected	Third party wear due to debris left in the wound could lead to Osteolysis, which leads to loosening of the implant and/or instability, requiring a revision. Increased level of constraint may be required

Our records indicate you may have received one or more of the affected products, which were distributed between the dates of August 2016 and September 2016.

Risk Manager Responsibilities:

1. Review this notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative quarantine all affected product.
3. Your Zimmer Biomet sales representative will remove the affected product from your facility.
4. Complete Attachment 1 – Certificate of Acknowledgement.
 - a. Return a digital copy to corporatequality.postmarket@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.
5. If after reviewing this notice you have further questions or concerns please call the customer call center at **1-877-946-2761** between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of the call center operating hours will receive a prompt to record a voicemail or be transferred to an on-call representative in the case of an emergency. Alternatively, your questions may be sent by email to corporatequality.postmarket@zimmerbiomet.com.



Other Information

This voluntary 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.

- MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: 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 zimmer.per@zimmerbiomet.com.

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

Sincerely,

<Printed Name and Title>

ATTACHMENT 1 Certificate of Acknowledgement

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

Hospital Facility **Surgeon** (Please check one as applicable)

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 email a copy to: corporatequality.postmarket@zimmerbiomet.com.