ZIMMER BIOMET

24 August 2017

To: Risk Managers

Subject: **URGENT MEDICAL DEVICE RECALL (REMOVAL) – LOT SPECIFIC**

Affected Product: Persona Tibial Plate Provisionals and Tibial Sizing Plates

Zimmer Biomet is conducting a medical device recall for specific lots of the Persona Tibial Plate Provisionals and Tibial Sizing Plates due to the potential for intermittent cracks in the raw material batch used to produce the affected products. The cleanliness of the affected products could be compromised if cracks penetrate the surface of the instrument as a result of the raw material issue. Use of this product may cause a delay of surgery less than thirty minutes or infection. The most probable outcome is no immediate or long-range health consequences expected.

AFFECTED ITEMS/LOTS		
ITEM	**LOT**	**DESCRIPTION**
42532108301	63535352	PERSONA STEMMED TIBIAL PROVISIONAL SIZE H LEFT
42532108301	63607357	PERSONA STEMMED TIBIAL PROVISIONAL SIZE H LEFT
42532108302	63613121	PERSONA STEMMED TIBIAL PROVISIONAL SIZE H RIGHT
42532108302	63683139	PERSONA STEMMED TIBIAL PROVISIONAL SIZE H RIGHT
42539908301	63531869	PERSONA CEMENTED TIBIAL SZ PLT SIZE H LEFT
42539908301	63576035	PERSONA CEMENTED TIBIAL SZ PLT SIZE H LEFT
42539908301	63649575	PERSONA CEMENTED TIBIAL SZ PLT SIZE H LEFT
42539908301	63693589	PERSONA CEMENTED TIBIAL SZ PLT SIZE H LEFT
42539908302	63531871	PERSONA CEMENTED TIBIAL SZ PLT SIZE H RIGHT
42539908302	63576041	PERSONA CEMENTED TIBIAL SZ PLT SIZE H RIGHT
42539908302	63688256	PERSONA CEMENTED TIBIAL SZ PLT SIZE H RIGHT

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

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 574-371-3071 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 medical device field action 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 even. 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.

The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your cooperation. We regret any inconvenience caused by this field action.

Sincerely,

Kevin W. Escapule
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

Affected Product: Persona Tibial Plate Provisionals and Tibial Sizing Plates | ZFA 2017-261

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

☐ **Hospital Facility**

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@zimmerbiometcom.