

August 14, 2017

To: Surgeons/ Hospital

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

Reference: ZFA2017-261

Affected Product: Persona Tibial Plate Provisionals and Tibial Sizing Plates

Zimmer Biomet is conducting a medical device field safety notice 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. **See Attachment 2, “Affected Product List” for a list of items/lots affected by this field safety notice.**



Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	No immediate health consequences expected	Delay of surgery less than 30 minutes
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	No long range health consequences expected	Infection

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.

Hospital 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 fieldaction.emea@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 contact your Zimmer Biomet representative.

Other Information

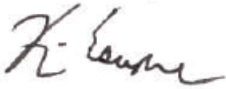
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing winterthur.per@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.

Thank you for your assistance. 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

 Surgeon *(please select)*

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: fieldaction.emea@zimmerbiomet.com.

Product Reference	Lot Reference	Number of products returned

ATTACHMENT 2
Affected Product List

Item Number	Lot Number	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