

July 12, 2018

**To:** Surgeons/Hospitals

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

**Reference:** ZFA 2017-00085

**Affected Product: Persona® Partial Knee System Spacer Block Alignment Tower**

Item Number	Lot Number	UDI Number	Item Description
42-5399-006-35	63465803	(01) 00880304809178 (10) 63465803	Persona® Partial Knee System Spacer Block Alignment Tower
42-5399-006-35	63762260	(01) 00880304809178 (10) 63762260	
42-5399-006-35	63767434	(01) 00880304809178 (10) 63767434	
42-5399-006-35	63799794	(01) 00880304809178 (10) 63799794	



Zimmer Biomet is conducting a lot specific medical field action (removal) for the Persona Partial Knee (PPK) System Spacer Block Alignment Tower. The PPK Alignment Tower mating feature that mates with the spacer block was found to be undersized, which could potentially lead to mating issues between the devices. There is another option in the surgical technique (1222.4-GLBL-en; page 13) for performing limb alignment without the alignment tower.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	Delay in 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
	None	None

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between November 2016 and March 2018.

### Surgeon/Hospital Responsibilities:

1. Review this notification for awareness of the contents.
2. Assist your Zimmer Biomet sales representative to quarantine immediately all affected products.
3. Your Zimmer Biomet sales representative will remove the affected products from your facility.
4. Complete **Attachment 1 – Certificate of Acknowledgement**.
  - a. Return a digital copy to [fieldaction.emea@zimmerbiomet.com](mailto:fieldaction.emea@zimmerbiomet.com).
  - b. Retain a copy of the Certificate of Acknowledgement with your field action records in the event of a compliance audit of your documentation.
5. If after reviewing the notice you have further questions or concerns please contact your Zimmer Biomet representative.

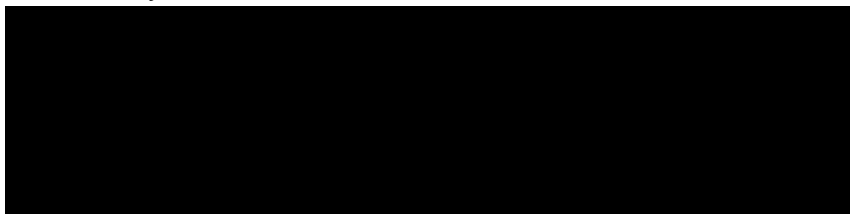
### Other Information

This 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](mailto: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. We would like to thank you for your co-operation in advance and regret any inconveniences caused by this field action.

Sincerely,



# ATTACHMENT 1

## Certificate of Acknowledgement

ZFA Reference: ZFA 2017-00085

**Affected Product: Persona® Partial Knee System Spacer Block Alignment Tower**

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

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

Printed Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Title: \_\_\_\_\_ Telephone: ( ) \_\_\_\_\_ - \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Facility Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_

City: \_\_\_\_\_ ZIP: \_\_\_\_\_ Country: \_\_\_\_\_

**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](mailto:fieldaction.emea@zimmerbiomet.com).

Even if you have no product to return, this form must be completed, signed and returned.

**Choose the following options:**

☐ All received products were discarded or lost by the clinic/ hospital

*Or complete the chart below for remaining products:*

Product Reference	Lot Reference	Number of products returned