



December 12, 2017

To: Surgeons / Hospitals

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE/ CORRECTION**
Phase 1

Reference: **ZFA2017-518**

Affected Product: : **Persona Partial Knee Spacer Blocks Size 8mm, 9mm, 10mm, 12mm, 14mm**

Item Number	Description	Lot Number
42-5399-035-08	PSN PK SPACER BLK, 8MM	63767442 63807190
42-5399-035-09	PSN PK SPACER BLK, 9MM	63769804
42-5399-035-10	PSN PK SPACER BLK, 10MM	63769805
42-5399-035-12	PSN PK SPACER BLK, 12MM	63769806
42-5399-035-14	PSN PK SPACER BLK, 14MM	63767443 63813674

Zimmer Biomet is conducting a **phased** medical device field action for the Persona Partial Knee Spacer Blocks Size 8mm, 9mm, 10mm, 12mm, and 14mm.

This notice (Phase 1) provides important information about the issue and the recommendation for continued clinical use of the affected items and lot numbers listed in the table above.

This letter will be followed by a removal notice (Phase 2) once adequate replacement supply is available.

Due to the available options for clinical use as outlined below, the affected spacer blocks do not need to be returned at this time and may continue to be used during Phase 1.

Issue Description

Complaints received indicated that the spacer blocks would not fit with the alignment tower or, in one case, the Persona Partial Knee handle. All affected lot numbers listed in the table above have the potential to exhibit this issue; however, not all spacer blocks will exhibit this fit issue with the mating instruments.

Recommendations for Clinical Use

There are two methods of checking limb alignment in the surgical technique:

1. The use of the alignment tower and alignment rod
2. Using only the alignment rods as detailed in Option #1 on page 13 of the surgical technique

The spacer block is designed with scallops or “finger grooves” in order to facilitate manual insertion and removal of the spacer block from the joint by hand, without the Persona Partial Knee handle.

Risks

The most probable immediate consequence of the issue is surgeon dissatisfaction (for those surgeons that routinely use the alignment tower), and the highest severity immediate health consequence could be a delay of surgery less than 30 minutes. There are no long-range health consequences.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed from August and November 2017.

It is important to note that this notification is an acknowledgment of the issue (Phase 1).

You will receive a follow up notification when the removal phase of the recall is initiated (Phase 2). During the removal phase, you will receive replacement spacer blocks.

Hospital Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. **Product does not need to be returned at this time.** You will receive a follow-up notice when the removal phase is initiated and it is time to return affected product (Phase 2). If you identify a spacer block that will not assemble with these instruments, and you are unwilling to use the spacer block without this functionality, the spacer block may be returned to your sales representative.
3. Complete **Attachment 1 – Certificate of Acknowledgement (Phase 1)** and send to fieldaction.emea@zimmerbiomet.com.
4. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
5. If you have further questions or concerns after reviewing this notice, please contact your Zimmer Biomet representative.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. The spacer block may be used without the alignment tower and inserted and removed by hand from the joint, without the Persona Partial Knee handle. If you identify a spacer block that will not assemble with these instruments, and you are unwilling to use the spacer block without this functionality, the spacer block may be returned to your sales representative.
3. There are no specific patient monitoring instructions related to this field action that are recommended beyond your existing follow-up schedule.
4. Complete **Attachment 1 – Certificate of Acknowledgement (Phase 1)** and send to fieldaction.emea@zimmerbiomet.com.
5. Retain a copy of the acknowledgement form with your field action records in the event of a compliance audit of your facility's documentation.
6. If you have further questions or concerns after reviewing this notice, 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 instrument or any other Zimmer Biomet product by emailing product.experience@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,

A handwritten signature in black ink, appearing to read 'K. Escapule'.

Kevin Escapule
Post Market and Regulatory Affairs Director



ATTACHMENT 1
Certificate of Acknowledgement
(Phase 1)

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Persona Partial Knee Spacer Blocks | Field Action Reference: ZFA 2017-518

Please select:

Hospital Facility Surgeon

By signing below, I acknowledge understanding of the information and responsibilities outlined in this recall notice, including the option for continued use of the affected spacer blocks during Phase 1.

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 is closed for your account. It is important that you complete this form and email a copy to fieldaction.emea@zimmerbiomet.com

Please select (as applicable):

A non-functioning Spacer Block was returned to our sales representative