

July 14, 2017

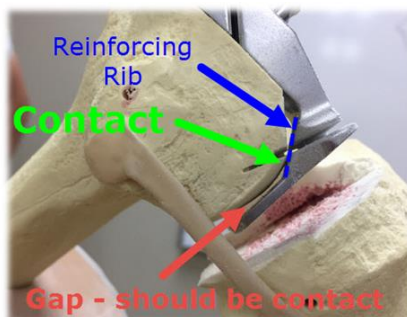
To: Surgeons/ Hospitals

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

Affected Product: Persona Partial Knee Femoral Finishing Guide (Size 8)

Item Number	Lot Number	Description
42-5781-008-01	63518668	PSN PK FEM FIN GDE, LM, S
42-5781-008-02	63518669	PSN PK FEM FIN GDE, RM, S

Zimmer Biomet is conducting a medical device field action for the Persona Partial Knee Femoral Finishing Guide (size 8). More specifically, two complaints were received that indicated that the flexion gap felt “tight” during implantation, which resulted in difficulty inserting the 2mm end of the tension gauge into the flexion space after implant placement. This issue has been attributed to a lack of sufficient posterior resection with the femoral finishing guide for the size 8 femur. The reinforcing rib has the potential to interfere with the posterior surface of the femoral bone, causing it to shift the cut points and lug drill points posteriorly (as seen in the picture below). The size 8 has been used in less than 1% of Persona Partial Knee cases. Sizes 1 through 7 do not have the reinforcing rib; therefore, they are not affected.



Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Surgeon notices tightness and downsizes femoral implant or increases posterior slope, or changes polyethylene	Limited range of motion due to tightness in the joint when knee is in flexion
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 injury expected	Limited range of motion due to tightness in the joint when knee is in flexion

Our records indicate that you may have received one or more of the affected instruments. The affected instruments were distributed between December 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.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. Use the size 7 and accept the reduced anterior coverage. This under-hang will not have an effect on function.
 - a. Per the surgical technique, there should be 2-3 mm uncovered bone anterior to the implant.
3. If you have implanted a size 8, patients should be monitored for achieving proper range of motion at your routine follow-up intervals.
 - a. A tight flexion gap will not always occur when implanting a size 8; this may not have happened with your cases.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@zimmerbiomet.com.
5. Retain a copy of the acknowledgement form with your recall 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

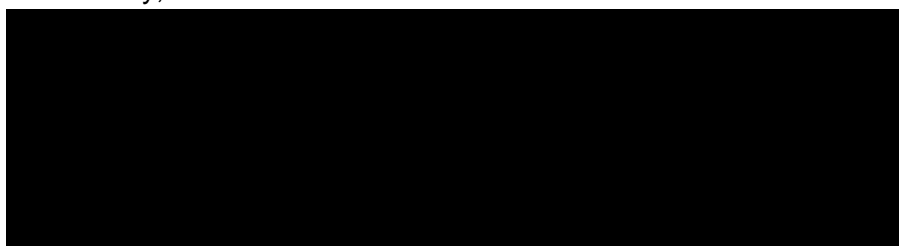
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices.

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,



ATTACHMENT 1
Certificate of Acknowledgement
ZFA2017-258

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

☐ Hospital Facility ☐ Surgeon

Printed Name: _____ Title/Function: _____

(mandatory)

Signature: _____ Date: ____/____/____

Telephone: () ____ - ____

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.

Product Reference	Lot Reference	Number of products returned