ZIMMER BIOMET

9 November 2017

To: Surgeons/ Hospital

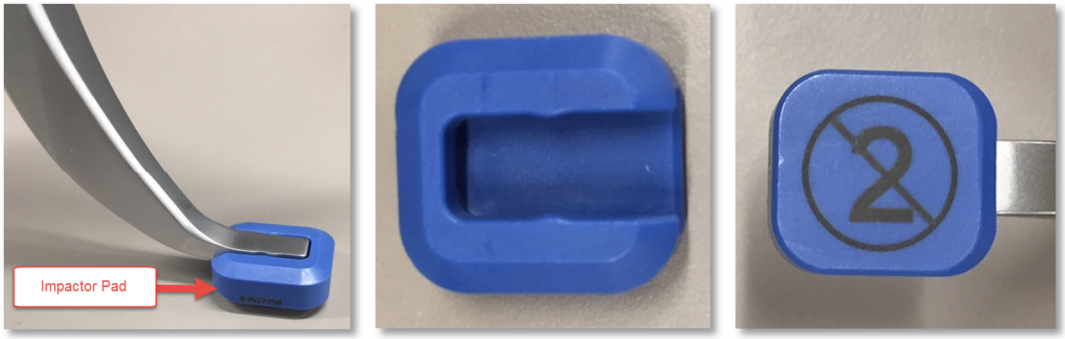
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE- CORRECTION**

Affected Product: Persona Partial Knee Impactor Pad

Item Number
42539909100

Zimmer Biomet is conducting a medical device **correction** to update the surgical technique for the Persona Partial Knee Impactor Pad due to the potential for the pad to fracture. The issue is easily identifiable by users, and the impactor pad is made from Radel Blue, which is readily visible against human tissue to aid in the extraction of any fragments. As a result of this issue, the surgical technique has been updated to provide additional assembly instructions and to emphasize that the impactor pad is a single-use product provided non-sterile.

Please refer to Attachment 2 for a detailed list of changes to the Persona® Partial Knee surgical technique.



Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	Delay of surgery less than 30 minutes	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 injuries expected	Pain, limited range of motion leading to surgical intervention to remove a fragment left in a patient

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between January 2017 and July 2017.

Hospital and Surgeon Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. Ensure that the most updated Persona® Partial Knee surgical technique is used, effective immediately, for surgeries that require the affected item.
    a. See Attachment 2 for a detailed list of changes to the surgical technique.
    b. Access the full surgical technique by contacting your Zimmer Biomet sales representative.
    c. Destroy any outdated copies of the surgical technique.
3. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.emea@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility.
4. Retain a copy of the acknowledgement form with your recall 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 Sales Representative.

Other Information

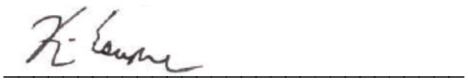
This voluntary medical device Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing 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,



Kevin Escapule,
Post Market Surveillance & Regulatory Compliance Director

ATTACHMENT 1
Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: Persona Partial Knee Impactor Pad **Field Action Reference:** ZFA 2017-312

Please check one as applicable:

☐ Hospital Facility ☐ Surgeon

By signing below, I acknowledge that the required actions have been taken in accordance with this Medical Device Correction notice.

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

ATTACHMENT 2
Changes to the Persona® Partial Knee Surgical Technique

1. Additional Visual Assembly Instructions Included (Page 29)

Supplementary visual figures have been added to exhibit the proper assembly of the impactor pad to the tibial plate impactor.

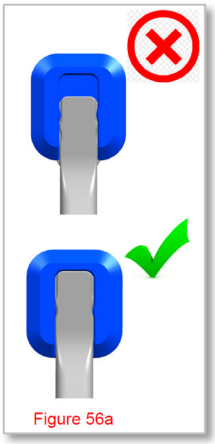


Figure 56a

2. Additional Written Assembly Instructions Included (Page 29)

The text “With the impactor pad assembled to the Tibial Plate Impactor” has been replaced with the following specific instructions for assembling the pad to the impactor:

> Assemble the blue single-use impactor pad to the tibial plate impactor. Complete and proper assembly is confirmed with an audible click. The tibial plate impactor will be inserted into the impactor pad when the click is heard, such that the tip of the metal tibial plate impactor is contacting the back of the “U” shaped groove in the impactor pad (Figure 56a).

3. A “Note” Added Regarding Single-Use, Non-Sterile (Page 29)

A note has been added to clarify that the impactor pad is for single-use only and must be disposed of after use:

> **Note:**
> The blue impactor pad is a single-use item provided non-sterile. Instrument must be cleaned and sterilized prior to use and disposed of following use.

4. Added Clarifying Words to Ordering Information “Disposables” Section (Page 43)

- Added the term “Single-Use” before the heading “Disposables (Ordered Separately)” so that it reads “Single-Use Disposables (Order Separately)”
- Added the words “Provided Non-Sterile” on the line item for the Persona Partial Knee Tibia Impactor Pad.