ZIMMER BIOMET

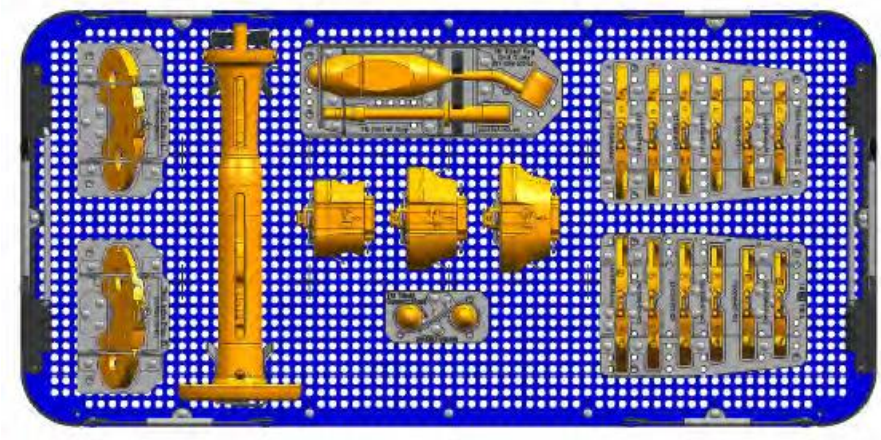
May 25, 2016

To: **Risk Managers**

Subject: **URGENT FIELD SAFETY NOTICE – PART NUMBER SPECIFIC**

Affected Product: **Persona™ Trabecular Metal™ Tibial Plate Select Instruments (See Addendum A)**

Zimmer Inc. is initiating a recall of specific Persona™ Trabecular Metal™ Tibial Plate Instruments and Modular Brackets. In February 2015 Zimmer initiated a recall of Persona™ Trabecular Metal™ Tibial Implants due to incidents of radiolucent lines and loosening higher than Zimmer's expectations and experience based on Zimmer's similar devices. Further investigation into the reported issue indicated that the instrumentation used to prepare the bone for the Persona™ Trabecular Metal™ Tibial Plate Implant, and to implant the Persona™ Trabecular Metal™ Tibial Plate could be related to the reported issue.



Representation of the Persona™ Trabecular Metal™ Tibial Plate Instrument Tray

Risks		
Immediate health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	Implant does not have appropriate initial fixation causing patient pain
Long range health consequences (injuries or illness) that may result from use of or exposure to the device issue.	Most Probable	Worst Case
	None	Implant never achieves appropriate biological fixation, leading to revision surgery

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. Assist your Zimmer Biomet sales representative with the quarantine of any affected product from Addendum A.
3. Your Zimmer Biomet sales representative will remove the recalled product from your facility.
4. Complete the Certificate of Acknowledgement Form (Attachment 1) and return to fieldaction.emea@zimmerbiomet.com.
5. **If after reviewing this notification you have further questions or concerns please contact your local Zimmer Biomet representative.**

Vigilance Information

This voluntary notification will be reported to the local Competent Authorities.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 8 to the local health authority in your country.

Please keep Zimmer GmbH informed of any adverse events associated with this device or any other Zimmer Biomet product. Adverse events may be reported to Zimmer Biomet at winterthur.per@zimmerbiomet.com, or to your local Zimmer Biomet representative.

ATTACHMENT 1

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Certificate of Acknowledgement:

Affected Product: Persona™ Trabecular Metal™ Tibial Plate Select Instruments

By signing below, I acknowledge that the required actions have been taken in accordance with the Recall Notice.

Printed Name: _____ Signature: _____

Title _____ Telephone: ( ) _____-_____ Date: ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ State: _____ ZIP: _____

Note: This form and affected product must be returned to Zimmer Biomet before this action can be considered closed for your account. It is your responsibility to complete this form and email a copy to: fieldaction.emea@zimmerbiomet.com**, in addition to including a copy with your product returns. Clearly mark the outside carton of each product return shipment made as "Recall." Please keep a copy of your completed form for your records.**

Please do not return recalled product with other returns.

ZFA 2016-96

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ADDENDUM A

Instrument Ref.	Instrument Name	Modular Bracket Ref. to Return
42-5398-064-01	TM Tibia Sizing Plate Left C	00-5907-081-76
42-5398-067-01	TM Tibia Sizing Plate Left D	
42-5398-071-01	TM Tibia Sizing Plate Left E	
42-5398-075-01	TM Tibia Sizing Plate Left F	
42-5398-079-01	TM Tibia Sizing Plate Left G	
42-5398-083-01	TM Tibia Sizing Plate Left H	
42-5398-088-01	TM Tibia Sizing Plate Left J	00-5907-081-85
42-5398-064-02	TM Tibia Sizing Plate Right C	00-5907-081-77
42-5398-067-02	TM Tibia Sizing Plate Right D	
42-5398-071-02	TM Tibia Sizing Plate Right E	
42-5398-075-02	TM Tibia Sizing Plate Right F	
42-5398-079-02	TM Tibia Sizing Plate Right G	
42-5398-083-02	TM Tibia Sizing Plate Right H	
42-5398-088-02	TM Tibia Sizing Plate Right J	00-5907-081-86
42-5398-020-00	TM Tibia Peg Drill Guide	00-5907-081-78
42-5099-092-10	TM Tibia Inserter Handle	Bracket not to be returned
42-5398-001-00	Locking Tibia Impactor Pad A-D	00-5907-081-79
42-5398-005-00	Locking Tibia Impactor Pad E-F	00-5907-081-80
42-5398-007-00	Locking Tibia Impactor Pad G-H	00-5907-081-81