



March 03, 2015

To: Risk Managers and Surgeons

Subject: URGENT MEDICAL DEVICE RECALL

Affected Product: Persona Trabecular Metal™ Tibial Plate, all sizes (see Attachment 1 for a complete list)

Zimmer is initiating a voluntary recall of the Persona Trabecular Metal™ Tibial Plate as the current complaint rate (0.61%) for radiolucent lines and loosening is higher than Zimmer’s expectations and experience based on Zimmer’s similar devices. Affected product has been distributed from November 29, 2012 until January 23, 2015.

Out of the complaints received, 36% identified symptomatic radiolucent lines or were revised for loosening, 28% identified asymptomatic radiolucencies, 8% subsided, and 28% were inconclusive. Aseptic loosening of cementless tibial implant components is one of the most prevalent causes for revision in total knee arthroplasty and a number of factors may contribute to the loosening failure mode, including patient characteristics, rehabilitation protocol and compliance, surgical technique, and product features.



Persona Trabecular Metal™ Tibial Plate, all sizes

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 sales representative with the quarantine of any affected product.
3. Your Zimmer sales representative will remove the recalled product from your facility.
4. **If after reviewing this notification you have further questions or concerns please contact your Zimmer contact person.**

Vigilance Information

This voluntary notification will be reported to the U.S. Food and Drug Administration and 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 informed of any adverse events associated with this device or any other Zimmer product. Adverse events may be reported to Zimmer at zimmer.per@zimmer.com, or to your local Zimmer representative.

Kind regards

Doña M. Reust
Field Action Manager
Corporate Quality & Compliance



ATTACHMENT 1

Part Number	Description
42-5300-064-01	Persona Two-Peg Trabecular Metal™ Tibia, TM Size C, Left
42-5300-067-01	Persona Two-Peg Trabecular Metal™ Tibia, TM Size D, Left
42-5300-071-01	Persona Two-Peg Trabecular Metal™ Tibia, TM Size E, Left
42-5300-075-01	Persona Two-Peg Trabecular Metal™ Tibia, TM Size F, Left
42-5300-079-01	Persona Two-Peg Trabecular Metal™ Tibia, TM Size G, Left
42-5300-083-01	Persona Two-Peg Trabecular Metal™ Tibia, TM Size H, Left
42-5300-088-01	Persona Two-Peg Trabecular Metal™ Tibia, TM Size J, Left
42-5300-064-02	Persona Two-Peg Trabecular Metal™ Tibia, TM Size C, Right
42-5300-067-02	Persona Two-Peg Trabecular Metal™ Tibia, TM Size D, Right
42-5300-071-02	Persona Two-Peg Trabecular Metal™ Tibia, TM Size E, Right
42-5300-075-02	Persona Two-Peg Trabecular Metal™ Tibia, TM Size F, Right
42-5300-079-02	Persona Two-Peg Trabecular Metal™ Tibia, TM Size G, Right
42-5300-083-02	Persona Two-Peg Trabecular Metal™ Tibia, TM Size H, Right
42-5300-088-02	Persona Two-Peg Trabecular Metal™ Tibia, TM Size J, Right



Attachment 2

**Confirmation for Receipt of Urgent Safety Notification
FSN/FSCA: 1822565-02-10-2015-002-R**

Please complete and sign this document to confirm the receipt of this Notification

Please send this form to your local Zimmer contact.

Fax / Email: _____

Do not hesitate to contact Zimmer if you need further details.

This document confirms that you have received the Urgent Safety Notice on the product

Affected Product: Persona Trabecular Metal™ Tibial Plate.

I confirm that the relevant information was given to me by Zimmer, for the protection of the interests and safety of patients.

Hospital/Clinic name and address

Printed Name of Surgeon

Signature and Date