February 19, 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 call the customer call center at 1-877-946-2761. Hours of operation are Monday through Friday, 8 a.m. through 5 p.m. EST.**

Other Information

This voluntary recall will be reported to the U.S. Food and Drug Administration.

MedWatch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online:www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Under 21 CFR Part 803, manufacturers are also required to report any serious injuries where a device has contributed to or may have contributed to the event. 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.

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

Acknowledgement of Responsibility:

Affected Product: Persona Trabecular Metal™ Tibial Plate, all sizes

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

Printed Name:_____ Signature:_____

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

Note: It is important that you complete this form and email a copy to: CorporateQuality.PostMarket@Zimmer.com. Please keep a copy for your records.

ZFA 2015-15