



October 31, 2014

To: Risk Managers and Surgeons

Subject: URGENT MEDICAL DEVICE RECALL NOTIFICATION - LOT SPECIFIC

Affected Product: Persona Stemmed 5 Degree Cemented Tibia, various sizes (see Attachment 1 for a complete list)

Zimmer is initiating a voluntary lot specific recall due to a cleaning process validation failure. You are receiving this letter because our records indicate that you may have received the affected product.

An internal reconciliation at the conclusion of a failed cleaning validation identified 6 manufacturing lots that were mistakenly released to distribution from April 3, 2014 to July 30, 2014. The cleaning process in question failed to meet Zimmer internal statistical parameters for confidence and reliability. A Process Performance Index of 0.98 was obtained with a required Process Performance Index of greater than or equal to 1.10. The affected manufacturing lots are listed in Attachment 1.



Persona Stemmed 5 Degree Cemented Tibia, various sizes

Risks

- If debris is present on the implant and is not encapsulated in the applied bone cement or removed during pulsatile lavage, the debris may lead to osteolysis.

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

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Field Action Manager
Corporate Quality & Compliance



ATTACHMENT 1

Part Number	Lot Number	Description
42-5320-071-02	62625781	Persona Size E Right Stemmed 5 Degree Cemented Tibia
42-5320-079-02	62613813	Persona Size G Right Stemmed 5 Degree Cemented Tibia
42-5320-071-01	62625790	Persona Size E Left Stemmed 5 Degree Cemented Tibia
42-5320-075-01	62619031	Persona Size F Left Stemmed 5 Degree Cemented Tibia
42-5320-075-01	62619040	Persona Size F Left Stemmed 5 Degree Cemented Tibia
42-5320-079-01	62626696	Persona Size G Left Stemmed 5 Degree Cemented Tibia



ATTACHMENT 2

**Confirmation of Receipt of Notice of Urgent Safety
FSN/FSCA: 2648920-10-01-2014-003-R**

For confirmation of receipt of this notice, please complete and sign this document.

Please send this form to your Zimmer local contact.

Fax / Email: _____

Don't hesitate to contact Zimmer if you need further details.

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

Persona Stemmed 5 Degree Cemented Tibia, various sizes

I certify 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