November 26, 2014

To: **Risk Managers**

Subject: **URGENT MEDICAL DEVICE RECALL NOTIFICATION**

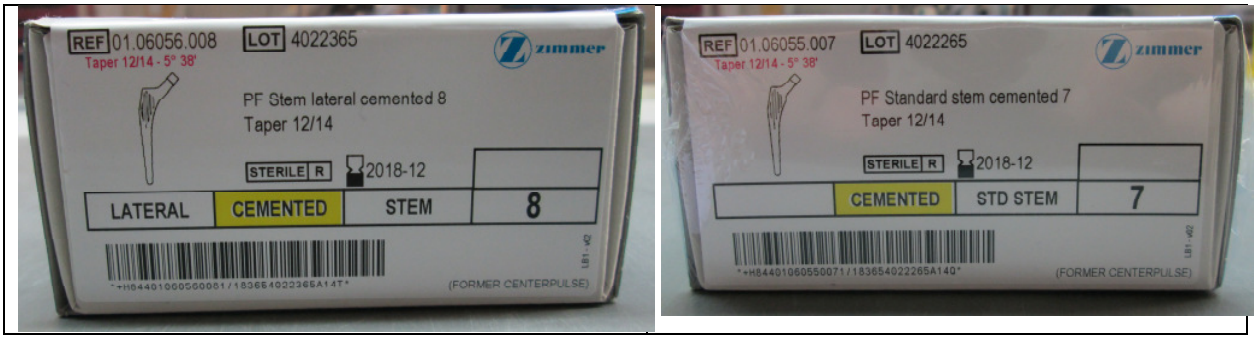
Affected Product:
PF Stem lateralized cemented size 8 (ref.: 01.06056.008, Lot 4022365)
PF Stem Standard cemented Size 7 (ref.: 01.06055.007, Lot 4022265)

Zimmer is initiating a voluntary recall of sterile-packaged implants due to a mix-up of the devices.

You are receiving this letter because our records indicate that you may have received the affected products. Records indicate that the affected products were distributed from January 2014 through September 2014.

Zimmer received one complaint regarding the mix-up of two batches from the same product family. The packaging was inspected, and it was discovered that the PF Stem Lateralized Cemented Size 8 packaging contained PF Stem Standard Cemented Size 7. Additionally, it was discovered that the PF Stem Standard Cemented Size 7 packaging contained the PF Stem Lateralized Cemented Size 8.

This mix-up could potentially lead to implantation of the incorrect device (for details see risk section below).



Risks
If the mismatch went unnoticed during surgery

<u>Case 1</u> – Surgeon planned for a surgery with the Size 8 Lateralized Stem but the Size 7 Standard Stem was available in the package.

- Loosening
- Dislocation

<u>Case 2</u> - Surgeon planned for a surgery with the Size 7 Standard Stem, but the Size 8 Lateralized Stem was available in the package

- Periprosthetic fracture
- Soft tissue tension causing pain

Follow up
Increased patient follow up is recommended

Your Responsibilities

1. Review the notification and ensure that relevant 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 local Competent Authorities within EU.

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,

[redacted]
Vice President
Quality Assurance and Regulatory Affairs – EMEA

ATTACHMENT 1

Confirmation for Receipt of Urgent Safety Notification
FSN/FSCA: FA 2014-01

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

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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