January 06, 2014

To: **Risk Managers**

Subject: **URGENT MEDICAL DEVICE RECALL-LOT SPECIFIC**

Affected Product: **Persona Cemented Tibial Broach Inserter/Extractor Handle (Instrument)**

Catalog Number: **42-5399-023-00**

Zimmer is initiating a voluntary lot specific recall of Zimmer Persona Cemented Tibial Broach Inserter/Extractor Handles due to the potential for disassociation of the magnet cover. You are receiving this letter because our records indicate that you may have received the affected product. Records indicate that the affected product was distributed from May 4, 2012 through December 19, 2012.

Zimmer received one complaint indicating the magnet cover of a Persona Cemented Tibial Broach Inserter/Extractor Handle was missing after broaching the tibia. An investigation into the disassociated magnet cover revealed a mismatch of print revisions that allowed for a clearance fit between the components. Not all current production and distribution is affected. The affected manufacturing lots are listed in Attachment 1.

Right: Persona Cemented Tibial Broach Inserter/Extractor Handle with disassociated magnet cover
Left: View of guide with disassociated magnet cover

Risks

The disassociated magnet cover is approximately 7.3 millimeters in diameter and 7.5 millimeters in depth. If the magnet cover disassociates and is not identified and removed from the patient, the following risks apply:

- Pain or irritation of soft tissues/soft tissue damage
- Increased implant wear
- Revision surgery to remove the magnet cover

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

[redacted]
Field Action Manager
Corporate Quality & Compliance

ATTACHMENT 1

Part
42-5399-023-00

Lots
62072307
62072565
62085420
62192754

ATTACHMENT 2

Confirmation for Receipt of Urgent Safety Notification
FSN/FSCA: 1822565-11-21-2014-017-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

Persona Cemented Tibial Broach Inserter/Extractor Handle (Instrument)

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