January 22, 2015

To: **Risk Managers and Surgeons**

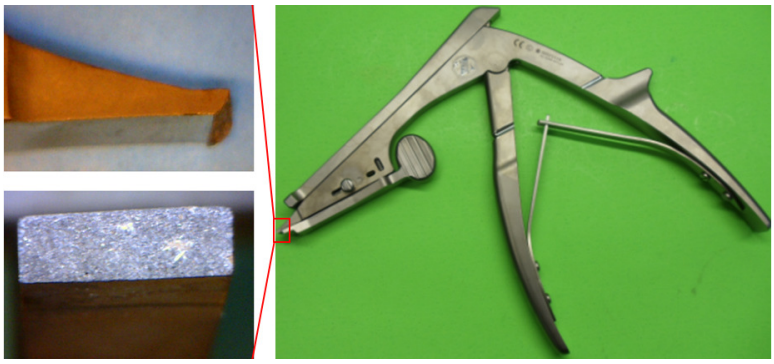
Subject: **URGENT MEDICAL DEVICE RECALL-LOT SPECIFIC**

Affected Product: **Persona Tibial Articular Surface Inserter (Instrument)**

Catalog Number: **42-5299-001-00**

Zimmer is initiating a voluntary lot specific recall of Zimmer Persona Tibial Articular Surface Inserters due to the potential for fracture of the tip. 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 February 5, 2014 through October 8, 2014.

Zimmer has received six complaints for fracture of the tip of Persona Tibial Articular Surface Inserters. The six complaints of fracture are for inserters supplied by the same manufacturer. An investigation into the issue revealed a difference in microstructure between the two suppliers of the inserter. All inserters supplied by the manufacturer with complaints for fracture are included in the scope of Attachment 1. Not all current production and distribution is affected. The affected manufacturing lots are listed in Attachment 1.



Right: Persona Tibial Articular Surface Inserter
Top Left: Side view of inserter after tip fracture, Bottom Left: Front view of inserter after tip fracture

Risks
The fractured tip is approximately 4mm x 7mm x 3.5mm in size. If the fractured tip is not identified and removed, the following risks apply:

- Pain or irritation of soft tissues/soft tissue damage due to contact with the fractured tip.
- Increased implant wear due to contact with the fractured tip.
- Revision surgery to remove the fractured tip.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. Inspect any product referenced within this notification before and after use for fracture of the tip. Provide any devices with a fractured tip to your Zimmer sales representative for return and replacement on a Product Experience Report (PER).
3. Replacement products are currently being manufactured. Reference Attachment 1 for the return date of affected lots.
4. Your Zimmer sales representative will remove the recalled product from your facility at the appropriate time.
5. **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
42-5299-001-00

Lots to be returned by March 30, 2015 per ZFA 2014-92	
56574123	56575018
56574124	56575056
56574538	56575057
56574540	56575058
56574618	56575059
56574619	56575060
56574620	56575061
56574629	56575062
56574630	56575065
56574631	56575080

ATTACHMENT 1

Confirmation for Receipt of Urgent Safety Notification
FSN/FSCA: 1822565-11-12-2014-015-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 Tibial Articular Surface Inserter (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