**April 20, 2015**

**To:** **Risk Managers**

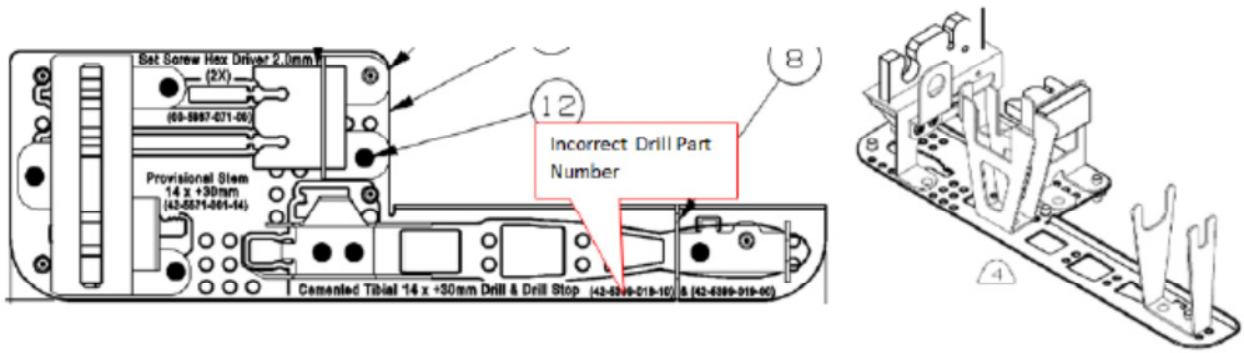
**Subject:** **URGENT MEDICAL DEVICE RECALL - LOT SPECIFIC**

**Affected Product:** **Persona Cemented Tibia Drill Bracket**

**Catalog Number:** **00-5907-083-69 Lot Number: 56570612**

Zimmer is initiating a voluntary lot specific recall of the Persona Cemented Tibia Drill Bit 15.7 +30mm Bracket due to the incorrect drill item number being etched on the bracket. The affected lot was distributed throughout Europe from March 14, 2014 through February 2, 2015.

The drill corresponding to the part number etched on the affected bracket is not intended to be used with the implants corresponding to this instrument tray.




| Risks | | |
|---|---|---|
| Immediate health consequences (injuries or illness) that may result if the incorrect drill is placed into the tray and subsequently utilized in surgery. | Most Probable | Worst Case |
| | None | Difficulty seating cemented implant or tibial fracture |
| Long range health consequences (injuries or illness) that may result if the incorrect drill is placed into the tray and subsequently utilized in surgery. | Most Probable | Worst Case |
| | None | Tibial fracture |

**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. Complete the Acknowledgement of Responsibility Form (Attachment 1) and return to fieldaction.emea@zimmer.com.
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 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.

# ATTACHMENT 1

## Acknowledgement of Responsibility

**FSN/FSCA: ZFA 2015-25**

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

**Affected Product: Persona Cemented Tibia Drill Bracket**

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

ZFA 2015-25