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August 19, 2014

To: **Surgeons and Theatre Managers**

Subject: URGENT MEDICAL DEVICE RECALL-LOT SPECIFIC

Affected Product: **Gender Solutions Patello-Femoral Joint System/Patello-Femoral Trochlea Component, Precoat, Size 4, Left, Part #00-5926-014-01, Lot #62455332**

Zimmer is initiating a voluntary recall of one lot of the Gender Solutions Patello-Femoral Joint System/Patello-Femoral Trochlea Component due to the potential that forged laps may exist in the identified lot of Patello-Femoral Joint (PFJ) components. A forged lap is a defect that forms when metal folds over itself during forging. You are receiving this letter because our records indicate that you may have received the Affected Product. The Affected Product was distributed between September 16, 2013 and October 22, 2013. No complaints or reports of injuries have been received to date

Internal review found that five (5) PFJ implant forgings were identified as having forged laps during receiving inspection processes for raw material. These five forgings were subsequently issued to final manufacturing to Part #00-5926-014-01, lot #62455332, consisting of sixteen (16) units.

Top View, PFJ component

Side view, PFJ component

Risks

- Immediate health consequences: The patient may be exposed to potential fracture of the implant upon implantation, which may lead to delay in surgery. Long-range health consequences: The patient may be exposed to potential cracking or fracture of the device *in vivo*; pain; restricted range of motion; a patella that catches, mal-tracks, or develops wear; implant loosening; need for revision; implant micro-motion; and/or patient dissatisfaction.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. Locate and quarantine any affected product listed above and notify your Zimmer sales representative.
3. Your Zimmer sales representative will remove the recalled product from your facility.
4. For patients that previously had this product implanted, it is recommended that you continue your normal postoperative follow up routine.
5. **If after reviewing this notification you have further questions or concerns please call the customer call center at 1-877-946-2761 between 8:00 am and 5:00pm EST.**

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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

Doña M. Reust
Field Action Manager
Corporate Quality & Compliance