August 26, 2013

To: **Surgeons**

Subject: **MEDICAL DEVICE Field Safety Corrective Action**

Affected Product: **Zimmer Trabecular Metal™ Reverse Glenosphere Distractor Instrumentation Used in Shoulder Replacement Surgery**

Item Number: 00-4309-049-00

Affected lot numbers:

60452884	60461858	60531990	60549559	60605842	60612781	60684768
60754281	60815778	60909547	60959086	60978338	61029048	61135953
61213252	61274877	61334929	61431672	61566464	61594740	61690097
61756058	61857748	61858851	61889174	61906350	61910781	61918666
62039450	62096379	62101249	62141887	62160965	62215378	62254111
62269856	62304206	62311096				

Zimmer is initiating a lot specific notification of the Trabecular Metal™ Reverse Glenosphere Distractor due to the potential of the device not functioning properly should it be utilized without proper lubrication. As a result, there is a potential for the device to fail to provide impact to the Glenosphere when the trigger is pulled. In addition, there is a potential for the foot of the device to fracture during use which may result in the device being unable to remove the Glenosphere. There have been 17 reported complaints of the device failing to provide impact and 8 reported complaints of the foot fracturing (worldwide).

Glenosphere Distractor

Fractured Foot

Risks

- If the device fails to provide impact to the Glenosphere or the foot fractures, the surgery could be delayed as an alternative device is obtained or as the fractured foot is located. Surgical delay of up to an hour has been reported.
- Inability to remove the Glenosphere with no immediate alternative method or instrument to remove the Glenopshere, may result in an additional surgery.
- Potential for unintended removal of the base plate and fixation screws when utilizing means other than the Distractor to remove the Glenosphere. If glenoid bone is unintentionally removed along with the base plate and fixation screws, further reconstructive surgery may be needed.
- If the fractured foot is implanted there is a risk of autoimmune reaction due to bio-incompatibility, as well as a possibility of revision surgery to remove fractured foot from the patient.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. If you find any product referenced within this notice, inspect before and after use for cracks at the foot and ensure the foot is intact. Also inspect immediately to ensure all moving parts are lubricated prior to each use according to

the Recommendations for Care, Cleaning, Maintenance, and Sterilization Manual 97-5000-170-00. If you find a device which does not function properly or has a damaged foot, provide it to your Zimmer sales representative for return to Zimmer on a Product Experience Report (PER).

3. Replacement products with a new design are currently being manufactured. Your clinic will be notified in the coming months once replacement product is available. At that time, you will be asked to return all affected devices in your possession at the time your new product is provided.
4. Your Zimmer sales representative will remove the recalled product from your facility at the appropriate time (Phase 2 of this field action).
5. **If after reviewing this notification you have further questions or concerns please contact your Zimmer contact person.**

Other Information
This voluntary notification will be reported to the U.S. Food and Drug Administration and to the local Competent Authorities.

Vigilance Reporting: 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.

Kind regards

Jaime Weeks
Post Market Surveillance & Regulatory Compliance Associate Director