July 31, 2013

To: **Surgeons**

Subject: **URGENT MEDICAL DEVICE RECALL**

Affected Product: **Zimmer Trabecular Metal™ Reverse Glenosphere Helmet, 36mm / 40mm Instrumentation Used in Shoulder Replacement Surgery**

Item	Lot
00-4309-071-36	All Lots Identified in Appendix A
00-4309-071-40	

Zimmer is initiating a lot specific recall of the Trabecular Metal™ Reverse Glenosphere Helmets due to the potential of one or both tabs fracturing during use. As a result, there is a potential for the tab to become disassociated from the device. There have been 47 reported complaints of tab fracture. In the U.S., these devices were distributed between July 27, 2007 and May 28, 2013.

Representative Tab Fracture

Risks

- Surgical delay up to 15 minutes to obtain an alternative helmet if the surgeon opts to insert the Glenosphere with the use of a helmet or to locate and remove the tabs from the patient.
- If the tabs or any fractured pieces are left in the patient, there is a risk of autoimmune reaction due to bioincompatibility as well as increased wear to the articular surface.
- Inability to sufficiently seat glenosphere if an alternative helmet is not available.
- Soft tissue irritation or damage.
- Pain.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. Please review the provided portion of the updated Trabecular Metal™ Reverse Shoulder surgical technique (97-4309-103-00) in Appendix B which notes proper Glenosphere installation technique. Following this technique significantly reduces the likelihood of helmet fracture. If preferred, a video is also available for viewing at https://www.zimmertv.com/videos/519.
3. If you find any product referenced within this notice, inspect before and after use for cracks and ensure the tabs are intact. If the product is damaged, provide it to your Zimmer sales representative for return to Zimmer on a Product Experience Report (PER).

4. Replacement products with a new design are currently being manufactured. Surgeons/ clinics 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.
5. Your Zimmer sales representative will remove the recalled product from your facility at the appropriate time.
6. **If after reviewing this notification you have further questions or concerns please contact your local Representative.**

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

[redacted]
Post Market Surveillance & Regulatory Compliance Associate Director

Appendix A: Lots included within recall

Item number 00-4309-071-36

60729528	60720059	60782350	60803204	60811712	60889765	60909408
60943022	60948237	60989841	60985366	61019823	61051119	61034821
61140638	61178017	61207698	61237374	61304005	61338570	61356591
61381187	61400935	61431685	61463330	61487660	61521267	61544005
61585968	61627734	61704564	61735029	61772406	61794587	61817713
61858701	61850103	61877862	61950512	61998686	61972672	62010251
62018071	62041751	62078963	62096387	62121179	62136094	62141873
62158509	62180443	62203390	62215390	62249372	62271566	62298060

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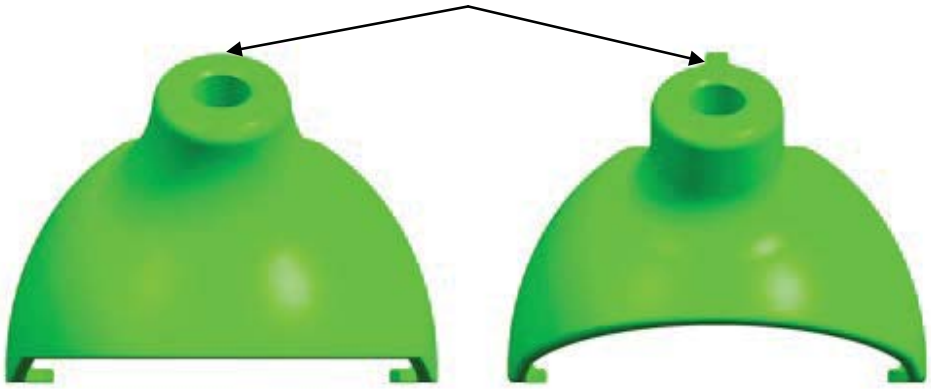
60720060	60729529	60782351	60875299	60902349	60948238	60943023
60985367	61019824	61034822	61063216	61145917	61183670	61207699
61218854	61356595	61400936	61515555	61566478	61615548	61756075
61780197	61832594	61864229	61923988	61978214	62041752	62136099
62180444	62226761	62289420				

The new design implemented a rib to facilitate easy identification of the new design versus the version being recalled.



Old Design (Recalled) **New Design (Replacement)**

Appendix B: Proper Glenosphere Insertion Technique per TM Reverse Shoulder Surgical Technique.

Implant Insertion

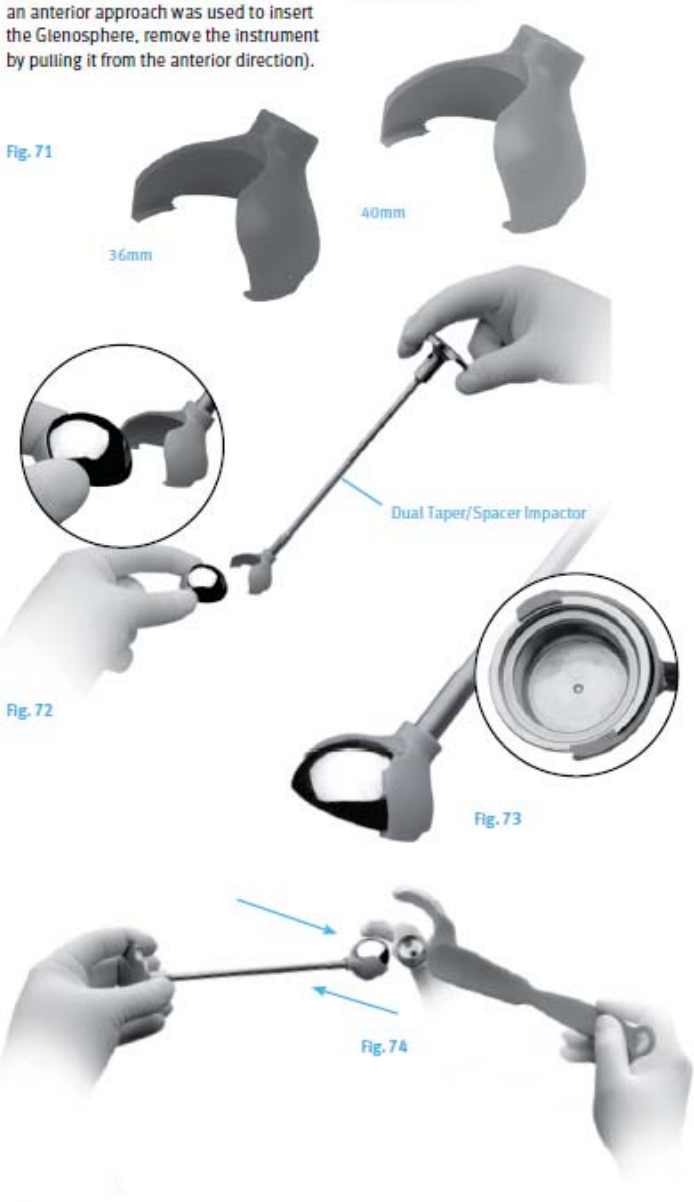
Glenosphere Assembly

The Glenosphere is typically inserted prior to humeral component final seating to maximize exposure of the glenoid and ease of insertion. Ensure all soft tissue is removed around the Base Plate to allow the Glenosphere to completely seat.

Assemble the Glenosphere Helmet Inserter by threading the Dual Taper/ Spacer Impactor into either the 36mm (green) or the 40mm (yellow) Glenosphere Helmet (Fig. 71). Insert the appropriate diameter Glenosphere into the helmet by sliding it into the helmet so that the Glenosphere is held in place by the body of the helmet and the tabs rest securely underneath the Glenosphere (Figs. 72 & 73). Wipe the Base Plate taper clean of all fluids and inspect the taper to ensure it is free of screatches or damage. Place the *Zimmer* Shoulder Shoehorn Retractor on the posterior side of the glenoid to aid in retracting the humerus and other soft tissue (Fig. 72). When approaching the Base Plate, a finger can be placed on top of the Glenosphere to help guide and feel the Glenosphere slide over the taper into position.

Note: While engaging the Glenosphere, it is important to monitor the position of the proximal humerus and provisional along with retractors since they could interfere with Glenosphere placement. Alternatively, a bone hook can be placed on the humeral provisional to draw the humerus laterally to provide clearance for the glenosphere. It's important to feel the mechanical resistance of taper engagement before proceeding to impaction.

Once the Glenosphere is seated evenly and circumferentially, use your free hand to press firmly on the Glenosphere to secure it to the Base Plate. Keeping a finger on the Glenosphere, remove the Glenosphere Helmet pulling the instrument away in the SAME DIRECTION used to insert the Glenosphere (i.e. If an anterior approach was used to insert the Glenosphere, remove the instrument by pulling it from the anterior direction). This will help minimize changes to the Glenosphere placement on the Base Plate and damage to the Glenosphere Helmet itself.



Note: If unable to visually confirm an even, circumferential engagement of the Glenosphere to the Base Plate, consider the use of a fluoroscope to aid in the confirmation. Seating of the Glenosphere to the Base Plate can be examined in the axillary view or in a view parallel to glenoid version. The medial rim of the glenosphere should be parallel to the face of the Base Plate (Fig. 75).

Assemble Glenosphere Impactor Head to the Impactor Handle and place the Glenosphere Impactor Head centrally on the Glenosphere. Strike the Glenosphere Impactor Head with 3 firm mallet strikes to engage the Glenosphere on the Base Plate (Fig. 76). Pull on the Glenosphere to verify the taper is locked. Reconfirm uniform engagement between the Base Plate and Glenosphere by using a small angled or 90 degree clamp to assess for malalignment gaps anterior to posterior, as well as inferior to superior.

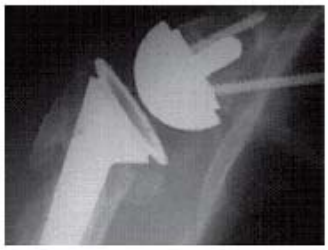


Fig. 75

Fig. 76

Glenosphere Removal

Should it become necessary to remove the Glenosphere, the Glenosphere Distractor can be used. Assemble the Glenosphere Distractor. Wedge the fin tip between the superior glenoid bone and the underside of the Glenosphere (Fig. 77). There must be good contact on these two surfaces for disengagement to occur. Pull the Glenosphere Distractor trigger until it fires. The Glenosphere head should be loose enough to gently remove by hand. If not, repeat the step making sure there is contact between the distractor tip, the glenoid bone surface and the Glenosphere head. Trial if necessary and implant the final Glenosphere as described on pages 19-21. Reduce the joint, and confirm range of motion. If all is satisfactory, continue on to the Closure Section.

Fig. 77

Humeral Stem Insertion

The final humeral preparation for a 130mm length *Trabecular Metal* humeral stem may be identical to a 130mm length Non-Porous Reverse humeral stem, allowing intra-operative flexibility between the two as a final implant. This includes preparation for the 10, 12, 14, 16 and 18mm sizes. When implanting an 8mm humeral stem, there are distinct proximal reamers for the two respective stems. The 8mm Non-Porous Reverse proximal reamer is marked with an etch reading "8MM NP" on the reamer shaft to differentiate it from the proximal reamer used for an 8mm *Trabecular Metal* humeral stem. The proximal geometry of the 8mm Non-Porous Reverse humeral stem is smaller than the 8mm *Trabecular Metal* humeral stem.

Cemented Technique
Humeral Preparation

If using a Cement Restrictor Plug, insert the plug one centimeter distal to the tip of the Humeral Stem. Thoroughly clean and dry the canal. Inject cement into the humeral canal. Use a finger to thoroughly pack the cement.

Note: Stem size is chosen based on cement mantle desired and the last reamers used.

Technique Tip: Be careful to avoid contact between the cement and the Trabecular Metal *material as the cement will interfere with the biological ingrowth properties of the material.*

Note: To avoid risk of a periprosthetic fracture, ensure the final humeral stem implant is not larger than the last Intermedullary Reamer used. Similarly, to avoid an overly loose canal fit, ensure the final humeral stem implant is not smaller than the last Intramedullary Reamer used.

Press-fit Technique

The Humeral Stem can be press-fit by sizing to the reamed diameter. Refer to sizing chart on page 4 for press-fit/clearance conditions.

Insertion for Cemented and Press-fit Techniques

Before inserting the final humeral component, drill any desired suture holes through the proximal neck of the humerus. Attach the Humeral Stem Inserter/Extractor to the Humeral Stem Implant by opening the handle all the way, inserting the stem inserter end into the proximal opening in the assembly, and closing the handle to lock the inserter in place (Fig. 78).

Fig. 78