zimmer

August 29, 2014

To: **Risk Managers and Surgeons**

Subject: URGENT MEDICAL DEVICE CORRECTION
UPDATED SURGICAL TECHNIQUES

Related Product: Zimmer® Persona Tibial Articular Surface Provisional Instruments
Item Numbers: See Attachment 2 for Listing of Item Numbers

You are receiving this letter because our records indicate that you may be a current user of the Zimmer Persona Knee System.

Zimmer launched the Persona Knee System in 2012, and since then Zimmer has received complaints related to the fracture of Tibial Articular Surface Provisional (TASP) Tops and Bottoms representing a complaint rate of approximately 0.82% since the products were introduced. The TASPs have been distributed from May 2012 to present.

Fractured TASP top and bottoms

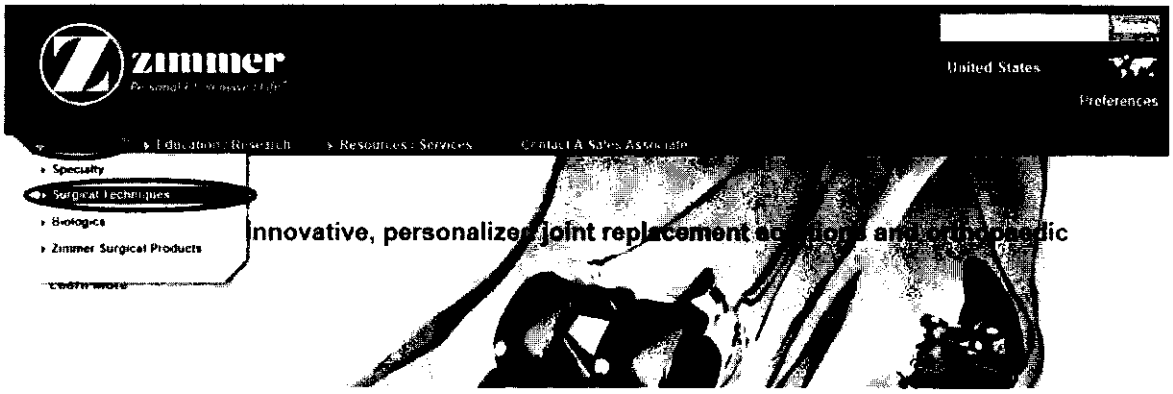
Based on the investigation results of these complaints, Zimmer determined that updates to device labeling associated with the Zimmer Persona Knee System were required to provide additional clarifications relating to the instructions for use of the TASP construct. Specifically, Zimmer has updated the Persona Surgical Technique (97-5026-001-00) and the Persona Constrained Posterior Stabilized (CPS) Surgical Technique (97-5026-072-00).

The following information is included in the surgical techniques:

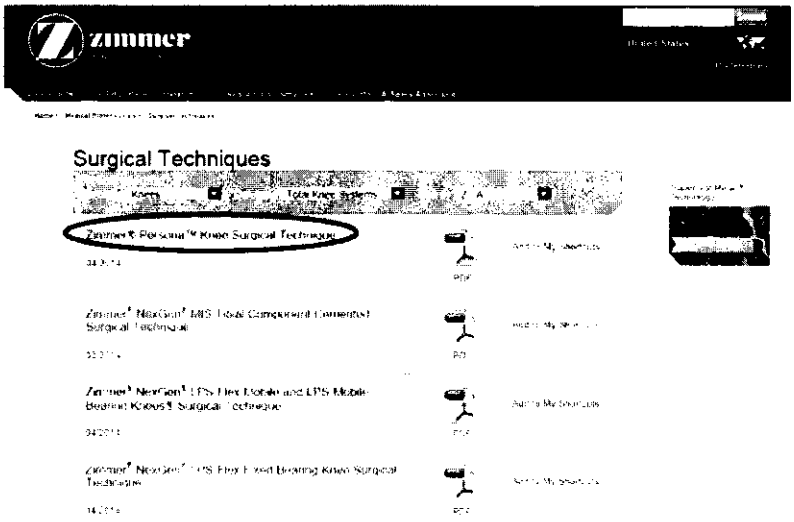
- **Apply gentle manual pressure without impacting the TASP construct with either a mallet or hand. The TASP construct includes the TASP top, bottom, shim, and Tibial Sizing Plate Handle.**
- **During assembly of the TASP construct, slide the shim in using a direct anterior approach between the TASP top and bottom. To avoid inadvertent separation, maintain slight pressure between the TASP top and bottom while inserting the shim.**
- **Varus/Valgus forces may make it difficult to remove the TASP construct. To aid in the removal of the TASP and prevent breakage, ensure that the joint is in a neutral position when removing the TASP construct.**

The translation of the new revision of the Surgical Technique is currently in progress. We estimate to finish the translating process by the end of October. At that time, you will find on your local website the updated version.
In the meantime, please store this FSN together with the Surgical Technique, or if you wish to view the whole Surgical Technique you can consult the English version available at Zimmer.com (see instructions below).

The surgical techniques in whole can be found by visiting www.zimmer.com, then selecting Medical Professionals, Products, and then Surgical Techniques.



The surgical techniques listed can then be sorted to find the appropriate technique.



The updated technique for use of the TASP construct and its components can be found on pp. 34-37 of the Persona Surgical Technique (97-5026-001-00, Rev. 8), and pp. 2-6 of the Persona Constrained Posterior Stabilized (CPS) Surgical Technique (97-5026-072-00, Rev. 1).

Risks
Risks associated with the fracture of the TASP tops and bottoms include:

- A minor delay in surgery
- A possibility for retained fragments from the TASP if there is a small piece that separates from the larger construct

The likelihood of injury in the event of device failure is less than remote.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. **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

Doña M. Reust
Field Action Manager
Corporate Quality & Compliance