



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.**

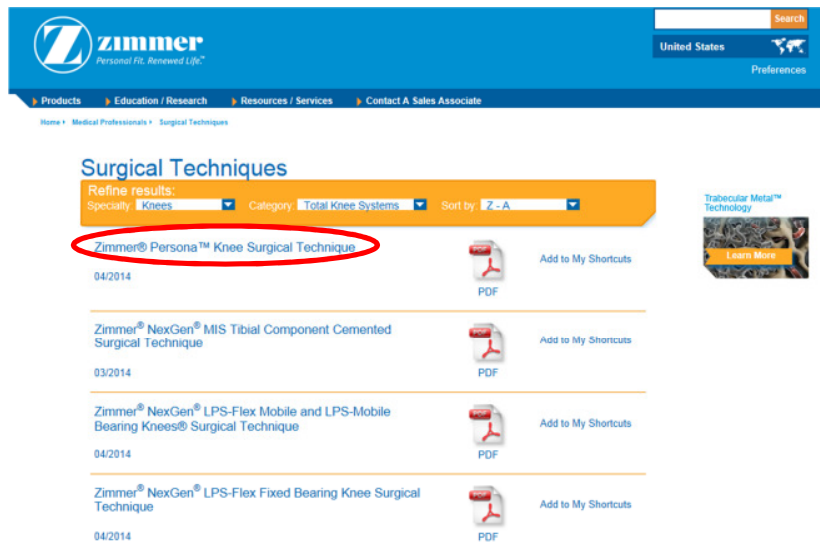
The translation of the new revision of the Surgical Technique is currently in progress. We estimate to finish the translating process by the end of October. At that time, you will find on your local website the updated version. In the meantime, please store this FSN together with the Surgical Technique, 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


Field Action Manager
Corporate Quality & Compliance



ATTACHMENT 1

List of Affected Surgical Techniques

- Persona Surgical Technique (97-5026-001-00)
- Persona Constrained Posterior Stabilized (CPS) Surgical Technique (97-5026-072-00).



ATTACHMENT 2

List of device associated with the affected Surgical Technique

The following item numbers are listed in order to help you to identify, if you are affected by this FSN. **Please note that the devices are not under the recall.**

Component Type	Part Number (No Dashes)	Item Description
CPS TASP BOTTOM	42517600303	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM L CD +0MM
	42517600313	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM L CD +6MM
	42517600505	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM L EF +0MM
	42517600515	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM L EF +6MM
	42517600707	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM L GH +0MM
	42517600717	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM L GH +6MM
	42517600909	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM L J +0MM
	42517600919	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM L J +6MM
	42527600303	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM R CD +0MM
	42527600313	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM R CD +6MM
	42527600505	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM R EF +0MM
	42527600515	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM R EF +6MM
	42527600707	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM R GH +0MM
	42527600717	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM R GH +6MM
	42527600909	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM R J +0MM
	42527600919	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional BOTTOM R J +6MM
CPS TASP TOP	42517600410	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP L 3-5 CD
	42517600510	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP L 6-9 CD
	42517600610	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP L 3-5 EF
	42517600710	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP L 6-9 EF
	42517600810	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP L 10-11 EF



Component Type	Part Number (No Dashes)	Item Description
	42517600910	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP L 6-9 GH
	42517601010	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP L 10-12 GH
	42517601110	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional TOP L 10-12 J
CPS TASP TOP (Cont'd)	42527600410	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP R 3-5 CD
	42527600510	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP R 6-9 CD
	42527600610	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP R 3-5 EF
	42527600710	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP R 6-9 EF
	42527600810	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP R 10-11 EF
	42527600910	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP R 6-9 GH
	42527601010	PERSONA™ The Personalized Knee System Constrained Posterior Stabilized Tibial Articular Surface Provisional TOP R 10-12 GH
	42527601110	PERSONA™ The Personalized Knee System Constrained Tibial Articular Surface Provisional TOP R 10-12 J
CR TASP TOP	42517000410	PERSONA™ The Personalized Knee System CR Tibial Articular Surface Provisional Left Size 3-9 CD Top
	42517000510	PERSONA™ The Personalized Knee System CR Tibial Articular Surface Provisional Left Size 3-11 EF Top
	42517000610	PERSONA™ The Personalized Knee System CR Tibial Articular Surface Provisional Left Size 7-12 GH Top
	42517000710	PERSONA™ The Personalized Knee System CR Tibial Articular Surface Provisional Left Size 9-12 J Top
	42527000410	PERSONA™ The Personalized Knee System CR Tibial Articular Surface Provisional Right Size 3-9 CD Top
	42527000510	PERSONA™ The Personalized Knee System CR Tibial Articular Surface Provisional Right Size 3-11 EF Top
	42527000610	PERSONA™ The Personalized Knee System CR Tibial Articular Surface Provisional Right Size 7-12 GH Top
	42527000710	PERSONA™ The Personalized Knee System CR Tibial Articular Surface Provisional Right Size 9-12 J Top
CR/UC/PS TASP BOTTOM	42517000303	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Left Size CD +0 mm Thickness Bottom
	42517000313	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Left Size CD +6 mm Thickness Bottom
	42517000505	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Left Size EF +0 mm Thickness Bottom
	42517000515	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Left Size EF +6 mm Thickness Bottom
	42517000707	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Left Size GH +0 mm Thickness Bottom
	42517000717	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Left Size GH +6 mm Thickness Bottom
	42517000909	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Left Size J +0 mm Thickness Bottom



Component Type	Part Number (No Dashes)	Item Description
	42517000919	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Left Size J +6 mm Thickness Bottom
	42527000303	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Right Size 1-2 CD +0 mm Thickness Bottom
	42527000313	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Right Size CD +6 mm Thickness Bottom
CR/UC/PS TASP BOTTOM (Cont'd)	42527000505	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Right Size EF +0 mm Thickness Bottom
	42527000515	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Right Size EF +6 mm Thickness Bottom
	42527000707	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Right Size GH +0 mm Thickness Bottom
	42527000717	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Right Size GH +6 mm Thickness Bottom
	42527000909	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Right Size J +0 mm Thickness Bottom
	42527000919	PERSONA™ The Personalized Knee System Tibial Articular Surface Provisional Right Size J +6 mm Thickness Bottom
PS TASP TOP	42517400410	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Left Size 3-5 CD Top
	42517400510	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Left Size 6-9 CD Top
	42517400610	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Left Size 3-5 EF Top
	42517400710	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Left Size 6-9 EF Top
	42517400810	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Left Size 10-11 EF Top
	42517400910	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Left Size 6-9 GH Top
	42517401010	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Left Size 10-12 GH Top
	42517401110	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Left Size 10-12 J Top
	42527400410	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Right Size 3-5 CD Top
	42527400510	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Right Size 6-9 CD Top
	42527400610	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Right Size 3-5 EF Top
	42527400710	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Right Size 6-9 EF Top
	42527400810	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Right Size 10-11 EF Top
	42527400910	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Right Size 6-9 GH Top
	42527401010	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Right Size 10-12 GH Top
	42527401110	PERSONA™ The Personalized Knee System PS Tibial Articular Surface Provisional Right Size 10-12 J Top
UC TASP TOP	42517200410	PERSONA™ The Personalized Knee System UC Tibial Articular Surface Provisional Left Size 3-7 CD Top



Component Type	Part Number (No Dashes)	Item Description
	42517200510	PERSONA™ The Personalized Knee System UC Tibial Articular Surface Provisional Left Size 4-11 EF Top
	42517200610	PERSONA™ The Personalized Knee System UC Tibial Articular Surface Provisional Left Size 7-12 GH Top
	42517200710	PERSONA™ The Personalized Knee System UC Tibial Articular Surface Provisional Left Size 9-12 J Top
UC TASP TOP (Cont'd)	42527200410	PERSONA™ The Personalized Knee System UC Tibial Articular Surface Provisional Right Size 3-7 CD Top
	42527200510	PERSONA™ The Personalized Knee System UC Tibial Articular Surface Provisional Right Size 4-11 EF Top
	42527200610	PERSONA™ The Personalized Knee System UC Tibial Articular Surface Provisional Right Size 7-12 GH Top
	42527200710	PERSONA™ The Personalized Knee System UC Tibial Articular Surface Provisional Right Size 9-12 J Top



ATTACHMENT 3

**Confirmation of Receipt of Notice of Urgent Safety
FSN/FSCA: 1822565-07-10-2014-003-C**

For confirmation of receipt of this notice, please complete and sign this document.

Please send this form to your Zimmer local contact.

Fax / Email: _____

Don't hesitate to contact Zimmer if you need further details.

This document confirms that you have received the Urgent Field Safety Notice on the product

Zimmer® Persona Tibial Articular Surface Provisional Instruments

I certify that the relevant information was given to me by Zimmer, for the protection of the interests and safety of patients.

Printed Name of Surgeon

Signature and Date

Name of Hospital