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Urgent Field Safety Notice

Commercial name of the affected product

Zimmer *Natural Knee II*® Porous Tibial Baseplates

FSCA-identifier Zimmer FSCA 1822565-2007-001

Type of action Device Modification (Instructions for use)

Date: 13 November 2007

Attention: Surgeons who utilize the *Natural Knee II® System,* with a porous tibial baseplate used without bone cement and with supplementary screw fixation.

Details on affected devices:

6212-00/01-001/150
6212-00/01-002/250
6204-00/01-400/440
6214-00/01-600/640

Description of the problem:

Zimmer has received a number of reports of osteolytic lesions in the vicinity of the screws when the *Natural Knee II*® System is used with a porous tibial baseplate, without bone cement and with supplemental screw fixation. To date, 35 Vigilance reports have been filed in Germany, reporting revisions attributed to osteolysis, of N-K II components used in this way. As of November 2007, approximately, 66,200 N-K II tibial baseplates have been sold in Germany, including 16,800 porous tibial baseplates. Zimmer wishes to ensure that surgeons are aware of the potential for osteolytic lesions to occur with uncemented tibial baseplates, and that they are aware, specifically, of the risk associated with use of N-K II knees with porous tibial baseplates used without bone cement and with supplemental screw fixation.

N-K II Porous Tibial Baseplate item numbers include the following:

6212-00/01-001/150
6212-00/01-002/250
6204-00/01-400/440
6214-00/01-600/640

A number of studies have reported osteolysis after total knee arthroplasty without bone cement, including Peters et al. [1], Lewis et al.[2], Goldberg and Kraay[3], and Berger et al.[4]. The development of these lesions is frequently associated with the generation of wear debris. Zimmer has become aware of some cases of osteolysis associated with use of the tibial baseplate of the *Natural-Knee II* System (N-K II), used without bone cement and with supplemental screw fixation. The osteolysis typically appears as a contained lesion at the tip of the medial fixation screw.

Zimmer has extensively investigated the occurrence of these lesions, and has not been able to confirm a specific cause. However, given the relationship between wear debris and osteolysis, Zimmer is targeting reduction of wear debris as the best way of reducing the risk of the lesions.

Due to Zimmer's practice of incorporating state-of-the art enhancements into products as part of normal product development, Zimmer has, over the period of time since the original release of N-K II, made available improved products with features designed to reduce wear debris. Improved polyethylene, including highly crosslinked polyethylenes (*Durasul*® Highly Crosslinked Polyethylene and *Prolong*™ Highly Crosslinked Polyethylene), reduced-oxygen packaging to decrease oxidation of conventional polyethylene, and improved tibial baseplate surface finishes are improvements that Zimmer has implemented to minimize generation of wear debris.

Advise on action to be taken by the user:
Based on recently presented clinical research[5,6], Zimmer is recommending that surgeons who use porous N-K II tibial baseplates without bone cement and with supplemental screw fixation use tibial articulating surfaces made of highly crosslinked polyethylene.

Zimmer also recommends that surgeons who have noted osteolytic lesions associated with these tibial baseplates refer to a journal article by Rod Plaster, M.D., entitled "An Algorithm for the Classification and Management of Periprosthetic Bone Defects Following Primary TKA"[7] (manuscript submitted for publication). This article provides information on the classification of osteolytic lesions and guidance on the management of patients who exhibit them. Information from the article, prior to publication, may be accessed by contacting Zimmer, Inc.

References:

1. Peters, P.C. et al. "Osteolysis After Total Knee Arthroplasty Without Cement." *Journal of Bone and Joint Surgery*, 74-A:864-876,1992.

2. Lewis, P.L., et al. "Screw Osteolysis After Cementless Total Knee Replacement." *Clinical Orthopaedics and Related Research,* 321:173-177, 1995.

3. Goldberg, V.M. and M. Kraay. "The Outcome of the Cementless Tibial Component." *Clinical Orthopaedics and Related Research,* 428:214-220, 2004.

4. Berger, R.A., et al. "Problems with Cementless Total Knee Arthroplasty at 11 Years Followup." *Clinical Orthopaedics and Related Research,* 392:196-207, 2001.

5. Prince, E.J., et al. "Comparison of Highly Cross-linked Polyethylene in Total Knee Arthroplasty". Presented at: 74th Annual Meeting of the American Association of Orthopaedic Surgeons; February 2007; San Diego, CA.

6. Plaster, R, et al. "Natural Knee II: 10 yr Follow-up of First 110 patients Implanted Without Cement". Presented at: 8th EFORT Congress; May 2007; Florence, Italy.

7. Plaster R. et al. "An Algorithm for the Classification and Management of Periprosthetic Bone Defects following Primary TKA". Manuscript submitted for publication. Excerpt used with permission of Dr. Plaster.

Transmission of this Field Safety Notice:
The following information is to be provided to surgeons who utilize the *Natural-Knee II*® System, with a porous tibial baseplate used without bone cement and with supplementary screw fixation.

Contact reference person:

Questions about the use of the *Natural Knee II*® system or about patients who have been implanted with a porous tibial baseplate without bone cement and with supplemental screw fixation, may be addressed by contacting Zimmer Inc.

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The undersign confirms that this notice has been notified to the appropriate Regulatory Agency

[redacted]
Associate Director, Postmarket Surveillance
and Regulatory Compliance
Zimmer, Inc.
[redacted]