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Medical & Radiation Emitting Device Recalls

Class 2 Recall
NEXGEN COMPLETE KNEE
SOLUTION MIS TIBIAL
COMPONENTS, LOCKING
SCREW AND STEM
EXTENSIONS



Date Posted	September 13, 2010
Recall Number	Z-2409-2010
Product	<p>NexGen complete knee solution MIS total knee procedure stemmed tibial component fixed bearing precoat size 2, sterile, REF 00-5950-027-02, Zimmer Inc. Warsaw, IN.</p> <p>This device is indicated for patients with severe knee pain and disability due to: Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis. Collage disorders, and/or avascular necrosis of the femoral condyle. Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy. Moderate valgus, varus, or flexion deformities. The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. NexGen™ Tibial Trays may be used with or without bone cement (biological fixation). NexGen MIS Tibial Components and MIS Modular Tibial Plates and Keels are intended for cemented use only.</p>

Code Information

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**Recalling Firm/
 Manufacturer**

Zimmer Inc.
 1800 W Center St
 Warsaw, Indiana 46580-2304

**Reason for
 Recall**

The firm has received complaints of loosening of the implanted device requiring revision surgery. There have been 114 MDRs filed all reported that the device loosened and the patient required additional surgery to replace the device.

Action

The firm, Zimmer, Inc., sent an "URGENT DEVICE CORRECTION" letter dated April 26, 2010, to all customers. The letter described the product, problem and action to be taken by customers. The customers were instructed to destroy or disregard all previous versions of the surgical technique, review the attached revised surgical technique to familiarize yourself with the modifications and warnings, and complete and return the Health Care Professional Documentation Form via fax to Zimmer, Inc. at (574) 372-4265. (Note: Zimmer made a modification to the surgical technique and instructions for use. They added a warning to fully cement and pressurize the anterior and posterior surfaces of the tibial component, and to strongly recommend the use of a drop down stem extension. This change was completed and approved on April 23, 2010.)

For questions please contact Zimmer at 1-877-946-2761.

Quantity in Commerce

68,384 all products

Distribution

Worldwide distribution: USA including states of AZ, IL, IN, KY, MO, NE, NM, NY, OH, TX, VA, WA,

and WI; and countries of Austria, Belgium, France, Germany, Italy, Netherlands, Spain, Sweden, Switzerland, UK, Australia, China, Hong Kong, India, Japan, Korea, Malaysia, Nicaragua, Singapore, Taiwan and Thailand.