

# Zimmer Issues Update on Saint-Gobain's Recalled Ceramic Femoral Heads

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WARSAW, Ind., Jan. 28 /PRNewswire-FirstCall/ -- Based on information provided on January 16-24, 2002 by Saint-Gobain, a French manufacturer of ceramic femoral heads distributed by most major orthopaedic companies, Zimmer Holdings, Inc. (NYSE: ZMH) announced today that it is advising its customers to notify their patients of possible breakage of the femoral head component from one of Saint-Gobain's product batches. Saint-Gobain has advised Zimmer that this potential for breakage is due to their manufacturing process for that batch. Zimmer had voluntarily recalled the affected Saint-Gobain products in August, 2001. A typical hip replacement involves a femoral stem, a femoral head mounted on top of the femoral stem, and a cup, or socket, which is fitted into the patient's pelvis.

"While we are concerned by the information provided to us by Saint-Gobain and will deal with the business issues accordingly, our first obligation is to quickly bring this matter to the attention of surgeons and their patients," said Ray Elliott, Chairman and Chief Executive Officer of Zimmer. "We are advising surgeons to follow their patients closely and make them aware of the potential for breakage of these femoral heads over time."

According to information obtained from Saint-Gobain, approximately 234 zirconia femoral heads distributed by Zimmer since 1999 have the potential to break over time. Zimmer estimates that fewer than 100 of the 234 units were sold in the United States. According to these data presented by Saint-Gobain to Zimmer, a significant percentage of these 234 implants may break over the next several years. The first such products distributed by Zimmer were implanted in 1999. Since that time, of the 234 femoral heads identified, however, only four have failed. Zimmer estimates the affected femoral heads are involved in less than one out of every 1000 hip replacements done since 1999 where Zimmer products were used.

Zimmer said that it is providing a detailed update to the affected surgeons so they can notify their patients. In August 2001, Saint-Gobain announced a recall of nine batches of zirconia femoral heads distributed worldwide. Also in August, Zimmer, as a special precaution, chose to expand the recall to include all of Saint-Gobain's similarly processed zirconia femoral heads. Based on information confirmed on January 24, 2002, however, only one batch received by Zimmer has been identified as

having potential for a significant incidence of breakage, and the four breakages that have occurred to date were only from that batch.

"While our first priority is for the patient who may experience difficulty as a result of Saint-Gobain's product performance," said Elliott, "we will take all measures to recover from this manufacturer costs incurred as a result of this issue."

Zimmer, based in Warsaw, Indiana, is a global leader in the design, development, manufacturing and marketing of orthopaedic reconstructive implants and fracture management products. Orthopaedic reconstructive implants restore joint function lost due to disease or trauma in joints such as knees, hips, shoulders and elbows. Fracture management products are devices used primarily to reattach or stabilize damaged bone and tissue to support the body's natural healing process. Zimmer also manufactures and markets other products related to orthopaedic and general surgery. Zimmer was founded in 1927 and has more than 3,500 employees worldwide. For the year 2000, Zimmer recorded worldwide revenues of more than \$1 billion. Zimmer became an independent, publicly traded company on August 7, 2001, when it was spun off from Bristol-Myers Squibb.

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