Zimmer, Inc.

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URGENT DEVICE CORRECTION

July 22, 2008

Dear Surgeon:

Since we last wrote to you in May 2008 regarding the *Durom*® Acetabular Component ("*Durom* Cup"), Zimmer has completed an extensive investigation of clinical experience with this product and its conformance to specifications. We are able at this time to share with you key conclusions and actions with respect to the *Durom* Cup in the United States.

- **The results of our in-depth investigation have led us to conclude that additional surgical technique instructions and training are necessary in the United States, and we strongly recommend that U.S. surgeons stop implanting the *Durom* Cup until receiving such training.**
- **Zimmer will suspend marketing and distribution of the *Durom* Cup in the U.S., while we update product labeling to provide more detailed surgical technique instructions and implement a surgical training program for U.S. surgeons.**
- **The *Durom* Cup will continue to be marketed and distributed without interruption outside the U.S.**

Our investigation included clinical and radiographic data review from users of the *Durom* Acetabular system, including those who have been pleased with their results, as well as users who are experiencing a higher than desired rate of revision. A total of twelve clinical sites that were among those with the highest patient volume for *Durom* Cup implants in both the U.S. and Europe were visited so that the largest number of patient cases could be reviewed in the shortest amount of time. More than 3,100 cases were examined overall.

We have identified that the more successful users consistently execute crucial technique steps for *Durom* Cups in a specific manner. The steps include but are not limited to line-to-line reaming, use of trials in every case, proper cup position for this device, appropriate impaction techniques, and no repositioning. In addition to the clinical component of our investigation, Zimmer has thoroughly investigated the design and manufacturing processes associated with the *Durom* Cup. No evidence of a defect in the materials, manufacture, or design of the implant has been found.

The overall rate of revision surgery is approximately 0.6% of all the *Durom* Cups sold to date in the U.S. However, due to difficulties in gathering data and our review of the above mentioned sites, we believe this may underestimate the actual revision rate. Of the U.S. sites investigated (where every patient -- more than 1,300 -- was reviewed) that

employed the above described techniques, the combined revision rate is 1.5%. Conversely, the revision rate for other sites is 5.7%.

Zimmer has reviewed the results of its investigation with the U.S. Food and Drug Administration and will continue to update the Agency as we move forward. Revised product labeling to include more detailed surgical technique instructions will be the subject of a further communication to surgeons over the next several weeks. Zimmer also is developing a comprehensive surgical skills training curriculum, working with experts in the U.S. and in Europe, where the product has been available since 2003 with significant training support for hip resurfacing and large diameter head applications, and where clinical outcomes have been consistently positive. Following initiation of the new U.S. training program, the *Durom* Cup will be made available to surgeons as they complete training. We will update you shortly about the status of the new curriculum and how you will be able to access it in the future.

These actions will be the subject of a public announcement by Zimmer the evening of July 22nd (please see hard copy attached of an excerpt from a Zimmer press release and related information on the *Durom* Cup investigation). We recognize that communication around this issue will stir patient interest, and we are eager to assist and support your efforts to address the range of patient needs that may emerge over the next several weeks. We are implementing several related measures, including:

- Development of patient management guidelines, to assist surgeons in the ongoing evaluation of patients currently implanted with the *Durom* Cup. These are currently being finalized and will be distributed shortly.
- Provision of a brief guide to suggested patient conversation (attached), to assist you and your staff in effectively and efficiently addressing patient questions and concerns.
    - Please note that Zimmer will suggest that patients who were implanted with the *Durom* Cup or who believe they may have been implanted with the *Durom* Cup and are experiencing pain more than three months after surgery consult with their physician.
    - We also have expanded our existing *Durom* Cup toll-free information service to address the basic information needs of patients who wish to call the Company. We will continue to refer patients with medical concerns to their physicians.
- Direct support to patients who require or who have undergone revision surgery of *Durom* components. If you have such patients in your practice, please have them contact David Royster at Zimmer at (574) 372-4712 or david.royster@zimmer.com to discuss compensation for costs associated with their revision surgery.
- Outreach to relevant professional societies to ensure that their memberships have accurate information about the *Durom* Cup field action.

All monoblock metal-on-metal acetabular cups are recognized as technically challenging devices to implant. Reducing the risk of hip dislocation while conserving acetabular bone is a key benefit of these devices that must be weighed against the technique demands.

Certain aspects of implanting technique are crucial to the clinical success of the device. Please note that utilization of the *Durom* Cup in a hip resurfacing application has not received FDA clearance for use in the U.S.

We continue to believe based on the results of our comprehensive investigation that the *Durom* Cup is a safe and effective device when used as intended. However, Zimmer does recognize this is a challenging procedure and thus is strongly recommending surgeons seek further training before attempting further *Durom* Cup implantations.

If you have relevant clinical information, questions, or comments regarding this matter, please contact us via our *Durom* toll-free information line (1-866-946-5633). Alternatively, you also may contact us at durom@zimmer.com.

Sincerely,

Cheryl Blanchard

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Background on *Durom*® Cup Status

Zimmer Temporarily Suspends Marketing and Distribution of *Durom*® Acetabular Component in the United States to Update Labeling and Implement Surgical Technique Training

Zimmer Holdings, Inc (NYSE and SWX: ZMH) is temporarily suspending marketing and distribution of the *Durom*® Acetabular Component (*Durom* Cup) in the United States, while the Company updates labeling to provide more detailed surgical technique instructions to surgeons and implements its surgical training program in the U.S. The *Durom* Cup will continue to be marketed without interruption outside the U.S.

Zimmer is taking this voluntary action to address its concerns regarding reports of cup loosenings and revisions of the acetabular component used in total hip replacement procedures, in some patients who have been implanted with the *Durom* Cup in the U.S.

While many U.S. surgeons have had success implanting the *Durom* Cup, a subset have experienced elevated revision rates since the product was launched in the U.S. in 2006. These results contrast with product experience in Europe, where post-marketing data continue to show excellent clinical outcomes since the product launched in 2003. Following a comprehensive review of clinical experience and product conformance to specifications in the U.S. and Europe, Zimmer has found no evidence of a defect in the materials, manufacture, or design of the implant. The Company has identified that surgeons who regularly achieve the desired outcome with the *Durom* Cup consistently execute crucial technique steps and place the cup in a specific manner. Following its review, Zimmer has determined that revised surgical technique instructions and a surgical training program are required to more consistently achieve desired clinical results in the U.S. The Company has shared its review and conclusions with the U.S. Food and Drug Administration (FDA) and will continue to update the Agency.

While the Company believes the likelihood of currently implanted patients requiring revision is low, Zimmer has sent a letter to U.S. surgeons advising them to stop implanting the *Durom* Cup, until the updated labeling is issued providing more detailed surgical technique instructions and they receive training.

"The Company is taking the necessary steps to address the apparent surgical training need, so that patients in the U.S. can consistently experience the results for which the *Durom* Cup was developed, and which have characterized the majority of clinical experiences with this product to date," said David C. Dvorak, Zimmer Holdings President and Chief Executive Officer. "In parallel, we will work closely with U.S. surgeons to help them appropriately monitor and manage patients currently implanted with the *Durom* Cup."

Surgeon and patient support
Zimmer will provide clinical management guidelines to assist surgeons in the ongoing evaluation of patients currently implanted with the *Durom* Cup. The Company suggests that patients who were implanted with a *Durom* Cup or believe they may have been implanted with a *Durom* Cup, and are experiencing pain more than three months after surgery, consult with their physician. Patients seeking more information may contact Zimmer toll-free, 24 hours a day, seven days a week, at 1-866-946-5633.

Within the next several weeks, Zimmer will issue a further communication to U.S. surgeons providing them with updated labeling, which will include the more detailed surgical technique instructions. The Company is also developing a comprehensive surgical skills training curriculum, working with experts in Europe and the U.S. Following initiation of the new training program, the *Durom* Cup will be made available to surgeons as they complete training.

Background on Durom
Total hip arthroplasty (THA), or total hip replacement, is a common medical procedure performed on more than 442,000 patients in the U.S. each year, according to the Millennium Research Group report issued March 2008. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One historical issue in THA has been wear of the bearing. As THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear. Another issue with THA has been range of motion and instability that can lead to hip dislocation. Larger heads are inherently more stable than smaller heads and provide opportunity for greater range of motion of the joint. Because larger heads can generally cause more wear, the development of alternative bearing surfaces to improve wear has been important. Through development of products like the *Durom* Cup, improving range of motion and lowering risk of dislocation becomes more achievable.

The *Durom* Acetabular Component is a monoblock (constructed of a single piece of material) cup made of a cobalt chromium (CoCr) alloy and is designed for use in combination with Zimmer's *Metasul*® Metal-on-Metal Tribological Solution LDH™ (Large Diameter Heads) for THA. The design and material of the *Durom* Cup are key elements to its stability, wear resistance, and bone sparing characteristics. The *Durom* Cup has a pure titanium plasma-sprayed coating for fixation. In compliance with FDA requirements for abrasion testing of plasma-sprayed coatings, the coating on the *Durom* Cup sold in the U.S. has a slightly different structure and is slightly thicker (100 µm, or 0.1 mm) compared to that sold outside the U.S.

Data from clinical trials sponsored by Zimmer and conducted outside the U.S. have demonstrated no revisions with the *Durom* Cup in 386 cases, after two to seven years of

follow-up[i]. In addition, the Swedish Registry, an independent total joint registry, reports a 99.5 percent survivorship with the *Durom* Cup (222 patients with three-year follow-up).[ii]

The *Durom* Cup was launched in Europe in 2003 for hip resurfacing, a procedure that has been common practice in Europe for more than 15 years to provide patients with an earlier intervention alternative to total hip replacement. Hip resurfacing requires less bone removal than conventional THA, but necessitates a different surgical technique. The *Durom* System also was made available in Canada and Australia in 2003, India and Korea in 2005, and Argentina in 2006, with similar surgical technique training.

In the U.S., the *Durom* Cup was cleared for marketing in THA by the FDA in mid-2006. It has not received FDA approval for use in the U.S. as a hip resurfacing device. Like all metal-on-metal monoblock acetabular components, the technology and design parameters of the *Durom* Cup demand a surgical technique with a higher degree of precision and specificity compared to more common and familiar hip arthroplasty surgical techniques practiced in the U.S. Therefore, the *Durom* Cup requires training in implantation technique and cup placement for many surgeons who begin using the product and who otherwise may be expert in THA.

Durom Cup Investigation

In addition to a comprehensive review of clinical experience, which included analysis of standard post-marketing surveillance data from established international joint registries and direct evaluation of high volume clinical sites in the U.S. and Europe, Zimmer conducted a thorough investigation of the *Durom* Cup, including systematic evaluation of the manufacturing processes, design specifications, and production documentation.

Manufacturing processes were closely examined and the product was retested to ensure conformance to specifications such as cleanliness and dimensional requirements. In addition, the plasma-sprayed titanium coating was verified to meet requirements and compared to other plasma-sprayed coatings, and documentation from production lots was reviewed for any anomalies, with specific attention paid to lots involving known revisions. This investigation found no evidence of a defect in the materials, manufacture, or design of the implant.

The clinical investigation involved reviews of clinical sites in the U.S. and Europe, interviews with users of other metal-on-metal monoblock products to gain additional insight on the category of products, and a comprehensive literature review. The *Durom* Cup users sites were visited to review X-rays, analyze patient-reported data, and examine trends regarding cup placement. Interviews with surgeons were conducted to discuss the full range of clinical issues and experience that may affect outcome. These data were collected for the U.S. and Europe *Durom* Cup sites visited.

A total of twelve clinical sites that were among those with the highest patient volume for *Durom* Cup implants in both the U.S. and Europe were visited so that the largest number of patient cases could be reviewed in the shortest amount of time. Eight clinical sites

were reviewed in the U.S. and four in Europe. In the U.S., Zimmer reviewed data on more than 1,300 patients – approximately 10% of all U.S. procedures involving the *Durom* Cup to date. Similar information was gathered from the four European sites (one each in Belgium, France, Germany and UK) to better understand any differences in the clinical experience. More than 3,100 cases were examined overall.

Of the sites investigated in the U.S. that employed appropriate and necessary surgical techniques, Zimmer found that the combined revision rate was 1.5%. Conversely, the revision rate for the other sites was 5.7%.

"We continue to believe based on the results of our comprehensive investigation that the *Durom* Cup is a safe and effective device when used as intended," said Cheryl Blanchard, PhD., Senior Vice President, Research and Development, and Chief Scientific Officer. "With appropriate training support to surgeons, we are confident of achieving patient outcomes in the U.S. that are as consistent as what we have seen historically in Europe."

About Zimmer

Founded in 1927 and headquartered in Warsaw, Indiana, Zimmer is a worldwide leader in designing, developing, manufacturing and marketing orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products. Zimmer has operations in more than 25 countries around the world and sells products in more than 100 countries. Zimmer's 2007 sales were approximately $3.9 billion. The Company is supported by the efforts of more than 8,000 employees worldwide.

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[i] Zimmer, Inc. Data on File
[ii] Swedish Hip Arthroplasty Register Annual Report 2006; page 57