

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,

A handwritten signature in cursive script, reading "Cheryl Blanchard".

Cheryl R. Blanchard, Ph.D.
Sr. Vice President, Research and Development
Chief Scientific Officer
Zimmer, Inc.