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URGENT DEVICE CORRECTION - UPDATE

August 16, 2008

Dear Surgeon:

In our July 22, 2008 letter to you regarding the temporary suspension of marketing and distribution of the *Durom*[®] Acetabular Component (*Durom* Cup) in the United States, Zimmer announced it would take the necessary steps to address the surgical training needs the Company identified through its extensive clinical investigation. We are now pleased to provide you with updated product labeling on the *Durom* Cup, more detailed surgical technique instructions and specific information regarding a comprehensive surgical training program, which Zimmer has developed in collaboration with several experts.

Enclosed with this letter are updated surgical technique instructions (*Metasul*[®] *LDH*[®] Large Diameter Head with *Durom* Acetabular Component).

The updated surgical technique instructions are the subject of our Urgent Device Correction of July 22, 2008. Please discard all previous versions of surgical technique instructions for the *Durom* Cup in the U.S., including Surgical Technique # 97-1081-002-00 and “Tips and Pearls” # 97-1081-016-00 and # 97-1081-023-00 (DVD).

Also included with this letter are updated Instructions For Use (IFUs), commonly called package inserts or product labeling, for the *Durom* Cup and the *Metasul* Metal-on-Metal Tribological Solution *LDH* for Total Hip Arthroplasty. Both the enclosed surgical technique instructions and IFUs contain updated information based on the findings of our clinical investigation. If you have any questions about these updated materials, please contact us via the *Durom* Cup toll-free information line (1-866-946-5633) or at durom@zimmer.com.

Surgical skills training program

In addition to this updated documentation, we are launching a comprehensive surgical skills training curriculum, key elements of which are available to surgeons as of August 19, 2008. In collaboration with experts from the U.S. and Europe, we have produced training curricula to provide training through several different learning modalities. These modalities include an online surgical training module, Web cast training sessions with experts, surgical skills courses through The Zimmer Institute and surgeon-to-surgeon training.

As we have communicated, the *Durom* Cup will be made available upon completion of training. While each modality offers a unique learning opportunity, the minimum required training for resumption of product usage is completion of the online training course. We have developed a comprehensive, user-friendly, online program that addresses the most critical technique issues in a concise and clear manner that also provides ease of access and verification of comprehension through online assessment. However, we encourage surgeons to consider the additional training opportunities based on their comfort level with the product.

Following are the details of the available training programs.

- **Online Training:** This course will be offered starting Tuesday, August 19, 2008. It will review the critical aspects of the *Durom* Cup design, preoperative planning considerations and comprehensive information regarding the critical technique steps to implant the device. The program includes videos, information from the experts and questions to evaluate comprehension. **This is the minimum required training to resume product use.**

The Online Training module can be accessed at the following secure Web site. Please type the link into your Internet browser and login with your username and password information outlined below. Once you have logged in, instructions on how to use the training program will be given.

Link: <http://zols.zimmer.com/durom>

Your Username: Your Password:

Attached are more detailed instructions for accessing the training. If you have any questions or problems, contact the Zimmer Helpdesk (available 24 hours, seven days a week) at 1-800-999-0506. To help ensure the security of the system, upon completion of the online training course your user name and password will be reset. For future access or questions, please contact the Zimmer Helpdesk.

- **Web casts:** These courses will review information similar to the online course, followed by a *live* question and answer session with an expert. The Web casts have been designed specifically as a follow-up to the online training. Further information on Web cast availability will be provided soon.
- **The Zimmer Institute Surgical Skills Courses:** These courses offer a didactic learning session and hands-on experience with cadavers to practice implantation of the *Durom* Cup in a controlled environment. These courses also serve as a follow-up to the online training. The Zimmer Institute courses will be offered according to the following schedule (additional dates and locations will be offered):

- September 25 - Baltimore, MD
 - October 9 - Warsaw, IN
 - October 16 - Denver, CO
 - October 23 - Phoenix, AZ (location to be confirmed)
- **Surgeon-to-Surgeon Training:** These courses will offer one-on-one learning from an expert in the operating room and will include a pre-operative planning discussion, personal education on the crucial technique steps of product implantation and consultation with the expert.

To access the Web casts, surgical skills, and surgeon-to-surgeon courses, please contact your Zimmer sales representative for further information.

We are pleased to offer these new materials and training programs and hope that you find them useful in the continuing management of your patients. We want to sincerely thank you for your ongoing support and patience during their development.

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

Sincerely,



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