

### ***Durom* Acetabular Component**

Zimmer is temporarily suspending marketing and distribution of the *Durom*<sup>®</sup> Acetabular Component (*Durom* Cup) in the U.S. on a voluntary basis, 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.

While many surgeons have had success implanting the *Durom* Cup since it was launched in the U.S. in 2006, a subset have reported cup loosening and revisions of the acetabular component used in total hip replacement procedures. 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 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 surgeon letter and related information is available at [www.zimmer.com](http://www.zimmer.com).