



Zimmer, Inc.

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Dear Surgeon:

You are likely aware of a recent communication within the surgeon community from Dr. Larry Dorr highlighting his experience with our *Durom*[®] Acetabular Component.

The purpose of this letter is to update you on actions ongoing at Zimmer in response to complaints received about the *Durom* acetabular component.

Our foremost concern is that we provide safe and effective products available for use, and we take seriously all reports of this nature from our customers. In this instance, we have mobilized senior members of our Research, Development, and Quality teams to investigate the complaints. The results of the investigation will allow us to determine whether any corrective actions are necessary to ensure the ongoing safe and effective use of our products.

In this particular case, we are working with a number of experienced users of the *Durom* acetabular component to ensure that we have a full preview of the data and their experiences. We are also analyzing design history files and any other experience that we have. This obviously will take some time, but in the interim, we commit to inform you as soon as we make any significant conclusions from our investigation. Furthermore, if we determine that we need to take more aggressive action, we will do so.

We want to share with you some data concerning this product. The *Durom* acetabular component has been sold internationally since 2003. It has been sold in the US since 2006. The device sold internationally is identical to that sold in the United States except that the plasma spray coating on the U.S. offering is modified slightly to meet FDA abrasion testing requirements. There have been over 56,000 *Durom* acetabular components sold globally, with nearly 12,000 of these sold in the US. Of the 56,000 *Durom* acetabular components sold, approximately 41,000 have been employed in primary THA and 14,000 in resurfacing applications.

According to the 2006 report of the Swedish National Register, the revision rate of the international *Durom* acetabular component is 0.5% three-years post op. Additionally, Zimmer's internal outcome study database of the U.S. product shows a 0.625% revision rate, based on three acetabular revisions out of 480 surgeries performed by 13 surgeons. Also, in structured clinical trials sponsored by Zimmer, we have observed no acetabular revisions to date out of 386 international cases at two to seven years of follow-up.

We continue to scrutinize all relevant information. If you have relevant clinical information, questions, or comments regarding this matter, please contact us via a special telephone number we have established for surgeons (1-866-946-5633). Alternatively, you also may contact us at durom@zimmer.com.

We will provide more information about the status of our investigation as we learn more. Please be assured that patient safety is our number one concern and if at any time during our investigation we determine that patient safety is being compromised, we will take appropriate corrective actions.

Thank you in advance for providing us with any information that may prove helpful with our investigation.

Sincerely,

A handwritten signature in cursive script that reads "Cheryl Blanchard".

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