P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

August 9, 2006

«First_Name» «Last_Name», «Title»
«Company_Name»
«Address_Line_1»
«Address_Line_2»
«City», «State» «ZIP_Code»

Dear «Last_Name»:

On June 28, 2006, Zimmer initiated a product recall for multiple lots of *M/DN®, HGP II®*, and *Herbert®* Sterile screws. This recall was initiated because some units of product from these lots that were shipped to customers after September 2005 may have had compromised sterile barriers. All outstanding units of product from the affected lots were recalled, even though the condition only affected about 1 in 50 screws distributed from these lots.

We understand that some units from the recalled lots were used by your (facility/hospital). If a patient was implanted after September 2005 with a screw from one of the affected lots, a small added risk of infection may exist. We believe such an infection would manifest itself early in the postoperative period and should be treated through normal standards of care for infection, at the physician's discretion.

Our analysis of the affected product showed that the intermittent condition of a compromised sterile barrier typically would have been readily apparent to an end user. The *Tyvek®* sterile barriers would either already have been open upon removal from the outer box, or the barrier would have peeled back without resistance.

Zimmer continually monitors the safety and effectiveness of its devices in all phases and has taken a very conservative approach to addressing this issue. We have taken corrective actions to eliminate the causes that led to the recall. We look forward to continued service to your patient needs.

Sincerely,

[redacted]
Associate Director,
Post Market Surveillance and Regulatory Compliance