DePuy
a Johnson & Johnson company

DePuy International Ltd.
Number One
White Rose Office Park
Millshaw Park Lane
Leeds LS11 0EA
Tel: +44 (0) 113 387 7800
Fax: +44 (0) 113 387 7890

18th October 2007

To: Trust Chief Executives, the Clinical Director-Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers – Private Sector Hospitals

Subject: Voluntary recall of various DePuy polyethylene knee bearings

Product type: Orthopaedic Implant – Polyethylene bearing used for patients requiring a knee joint replacement

Description: See attached

Codes: See attached

Lots affected: See attached

In June of 2005, DePuy Orthopaedics, Inc. initiated a voluntary recall of polyethylene tibial inserts due to a loss of vacuum on the inner foil pouch. In addition to the recall and taking corrective actions to ensure the problem would not recur, DePuy Orthopaedics, Inc. undertook extensive sampling of existing inventories of the product affected by this issue. The final analysis of this sampling effort has identified additional lots that may be affected. Therefore, DePuy Orthopaedics, Inc. is expanding the scope of the original recall to include these additional lots.

This vacuum seal provides an oxygen-free environment for the polyethylene following gamma irradiation, reducing the potential for oxidation of the polyethylene. The outer barrier of the affected packages was never compromised, ensuring sterility of the insert. However, if the vacuum seal were incomplete, the polyethylene insert would likely be gamma irradiated in the presence of oxygen, which may result in unknown levels of oxidation of the polyethylene. Research indicates that extended shelf aging of gamma-in-air sterilised polyethylene can diminish long-term performance.

Further research indicates there is a critical oxidation index level where polyethylene fatigue damage can occur. Shelf aged, gamma-in-air irradiated components have been found to typically reach this oxidation index level after approximately 48 months. The average time between the date of manufacture and the date of sale for these products is 7 months. It is important to note that oxidation can continue following implantation, but the rate is variable and patient specific. Therefore, we believe that this incident will have minimal effect on the long-term performance of these parts.

The question of informing your patients is ultimately your decision. It is the aim of DePuy Orthopaedics Inc. to inform you of the facts as we currently understand them and allow you to make decisions regarding your patients. We greatly appreciate your understanding and support.

Sincerely,

[redacted]

[redacted]
On Behalf of DePuy International Ltd.