## **Important Safety Notice**Voluntary Product Recall - Total Knee®



March 31, 2006

Dear Customer,

Össur is implementing a worldwide voluntary recall of the 1100, 1900, 2000 & 2100 models of the Total Knee<sup>®</sup>.

Our decision to implement this recall is based on a finding that some units of the Total Knee contained faulty pins within the axis of the knee. No incidents or injuries resulting from this situation have been reported to the company. To date, the incidence of actual product failures within the recalled knees is less than one percent (<1%). Substantial analysis of the pin manufacturing process has been performed. Össur has increased testing requirements for the faulty part and additional measures have been put in place to guarantee the quality and safety of all new knees.

All serial numbers of the affected Total Knees have been identified and the recall applies only to those units manufactured from June 7<sup>th</sup>, 2005. If you are affected by this recall, an ACTION STATEMENT is attached to this letter. The action statement lists the serial numbers of the units you have purchased since June 7<sup>th</sup> and explains necessary actions to be taken to ensure patient safety. If no such statement is attached, it is confirmed that according to our records you are **not** affected by this recall. We still ask you to stay alerted in case a new patient wearing a Total Knee comes in for services at your facility. All serial numbers affected are listed on our website.

Össur takes the issue of patient safety very seriously. Therefore, we are implementing a replacement program where we will be substituting the affected knees with replacement units that will carry a two-year warranty from the date of fitting.

Your sales and customer service representatives are available to answer any questions you may have (Tel + 800 3539 3668 or +44 (0)161 232 7665). In addition, you can refer to our website: <a href="https://www.ossur.com">www.ossur.com</a> where we will be posting updates, as needed.

This recall is being conducted with the knowledge of the regulatory authorities.

Thank you for your understanding in this matter.

Olafur Gylfason Managing Director Össur Europe