

4 February 2010

Name
Title Dept
Hospital
Address 1
Address 2
Address 3
Address 4

Journey Uni Tibial Baseplates and Inserts

<u>Affected Part Numbers</u> Please see list below
<u>Affected Lot Numbers</u> All Lot Numbers

Dear Customer,

Smith & Nephew have launched a voluntary recall of our Journey Uni Tibial Baseplates and inserts. Based on Surgeon reports, the metal base plate of our Journey partial knee tibial base plate has a fracture rate of 0.1%. We are withdrawing these components from the market until we inspect 100% of the returned inventory and determine why they are not performing to our standards.

While it's still early in the inspection process, we have received reports that indicate that failures may present with or without pain or loss of function. We recommend you continue to utilize your standard follow-up protocol with your patients who have received Journey partial knee tibial base plate.

Our records show that this item has been despatched to you recently . To determine if this is so, please check your stock and isolate any items found. Please complete the declaration on the following page by inserting the number of items held and return the form to Tony Horn on Fax Number 01926 482490 .

The Medicines and Healthcare Products Regulatory Agency have been informed of this recall.

Yours sincerely,



Tony Horn

Quality and Regulatory Manager

Fax to Tony Horn, Smith & Nephew Orthopaedics UK, on 01926 482490. Please return this declaration by 28th February.

DECLARATION

I can confirm that I have the following numbers of affected items in our stock.
(please include a zero in the quantity column, if your stock is nil)

Product Code	Lot Number	Quantity
Bases 71422221, 71422222 71422223, 71422224 71422225, 71422226 71422231, 71422232 71422233, 71422234 71422235, 71422236 Inserts 71422241, 71422242 71422243, 71422244 71422245, 71422246 71422247, 71422248 71422251, 71422252 71422253, 71422254 71422255, 71422256 71422257, 71422258 71422261, 71422262 71422263, 71422264 71422265, 71422266 71422267, 71422268	All Lots	

Where applicable, these have been segregated awaiting shipping and return instructions from Smith & Nephew Customer Care Department, who have been contacted regarding this matter.

Signed

Print Name

Position

Organisation / Hospital

Date