

20th June 2007

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

Urgent Medical Device Recall

Birmingham Hip Resurfacing Acetabular Cups

All of the following one off Lot Numbers in the table below

Dear Customer,

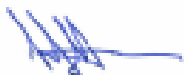
Smith & Nephew have been informed that the above devices may have been miss - labelled. The product packaging for the notified complaint was for a 54 mm BHR Acetabular Cup, however inside was a 50mm Acetabular Cup. One more device has also been positively identified as being the reverse of this.

An evaluation has been performed in-house and has determined that the devices are likely to cause a risk of adverse health consequences to the patient through the necessity for revision surgery. Due to the mismatch in size of the Femora I and Acetabular devices this may lead to elevated metal ion levels and or metallosis. Smith & Nephew are therefore recalling the above mentioned products to physically verify their status.

A number of the devices in the table below have been identified as being implanted. Smith & Nephew have contacted all of the surgeons and Hospitals which are affected by this recall. This will enable Smith & Nephew and the surgeons involved to review the patient X-rays and verify the status of these devices.

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

Yours sincerely,



Tony Horn

Regulatory Specialist

Lot No	Part No	Quantity	Description
64599	74120160	1	Acetabular Cup
65945	74120154	1	Acetabular Cup
65655	74120158	1	Acetabular Cup
64767	74120156	1	Acetabular Cup
65679	74120156	1	Acetabular Cup
65543	74120154	1	Acetabular Cup
65654	74120150	1	Acetabular Cup
65540	74120160	1	Acetabular Cup
65943	74120156	1	Acetabular Cup
63452	74120156	1	Acetabular Cup
66655	74120154	1	Acetabular Cup