Recalls

A hip implant may be recalled by the manufacturer for a number of reasons. If your hip implant is recalled, this does not necessarily mean that the implant needs to be removed and replaced. In some cases the recall recommends different or more frequent monitoring. It is important to discuss the reason for the recall with your orthopaedic surgeon to determine the most appropriate course of action.

For more information about FDA’s regulatory requirements and guidance, see Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm329946.htm).

Recalls Specific to Metal-on-Metal Hip Implants

- **Smith & Nephew R3 Metal Liners of the R3 Acetabular System**
- **DePuy ASR TM XL Acetabular System**
- **Zimmer Durom® Acetabular Component**

**Smith & Nephew R3 Metal Liners of the R3 Acetabular System**

On June 1, 2012 Smith & Nephew Orthopaedics initiated a market withdrawal for metal liners of the R3 acetabular system due to a higher than expected number of revision surgeries associated with the use of the device in total hip replacements outside the US.

Smith & Nephew is recommending that physicians maintain their usual follow-up protocol for patients who have undergone total hip replacement or resurfacing surgery.

In the US:

- The R3 metal liner is only approved for use with the Birmingham Hip Resurfacing System.
- The R3 Acetabular System is a total hip replacement system component that is not cleared for use with the R3 metal liner.
Additional information on this action can be found on Smith & Nephew’s website (http://r3.smith-nephew.com/professionals/index.html). The preceding link is to a website owned and operated by Smith & Nephew, Inc. The information contained therein does not express the views or opinions of the FDA.

DePuy ASR™ XL Acetabular System

On Aug. 24, 2010, there was a voluntary recall of the DePuy ASR™ total hip system because of new, unpublished data from the UK joint registry indicating the revision rates within 5 years were approximately 13 percent.

Note: UK joint registry data is indicative of revision rates only in the UK and may not necessarily directly correlate to revision rates in the US.

For additional information about this recall, as provided by DePuy, see ASR™ Hip System Recall Guide (http://asrrecall.depuy.com/node/20420). The preceding link is to a website owned and operated by DePuy Companies. The information contained therein does not express the views or opinions of the FDA.

Zimmer Durom® Acetabular Component

On July 22, 2008, there was a voluntary recall of the Zimmer Durom® Acetabular Component (“Durom Cup”) because the instructions for use/surgical technique instructions were inadequate.

For additional information, as provided by Zimmer, see Zimmer Inc. Surgeon Letter (http://www.zimmer.com/web/enUS/pdf/DUROM_SURGEON_LETTER_07-22-08_FINAL1.pdf) The preceding link is to a website owned and operated by Zimmer, Inc. The information contained therein does not express the views or opinions of the FDA.