

January 11, 2011

ASR™ HIP SYSTEM RECALL

1. PURPOSE: This Veterans Health Administration (VHA) Notice advises all staff that the Acetabular System and DePuy Hip Resurfacing System (ASR™) made and distributed by DePuy Orthopaedics has been voluntarily recalled.

2. BACKGROUND

a. On August 26, 2010, DePuy Orthopaedics, Inc., announced it is voluntarily recalling the ASR™ Hip Resurfacing System used in hip replacement surgery due to the number of patients who required a second hip replacement procedure.

b. The “recall” of the ASR™ hip does not necessarily mean the Veteran will need to have the hip implant removed. Most people with ASR hip implants do not experience problems. However, it is important that Veterans are followed up on an annual basis for the first 5 years after the ASR Hip surgery, even if the Veteran is not experiencing symptoms, to ensure that the Veteran’s hip continues to work well. Beyond 5 years, the follow-up would be in accordance with locally-agreed procedures.

c. In response to the voluntary recall of the DePuy ASR™ Hip Resurfacing System, the National Center for Patient Safety Product Recall Office posted a notice of recall to the VHA Alerts and Recalls Web site and sent a back-up e-mail communication to all VHA Facility Recall Coordinators on August 30, 2010, as identification number 386. All in-stock products were to be sequestered by September 14, 2010. Any devices in the possession of the Department of Veterans Affairs (VA) were to be returned to the vendor in accordance with manufacturer’s instructions. The DePuy ASR™ Hip Resurfacing System product is a consignment product so no costs were exchanged, merely the return of the product. As of November 9, 2010, all identified in-stock products were identified and sequestered.

3. BILLING PROCEDURES

a. Based on discussions with the Office of General Counsel, VA should continue to bill copayments (as appropriate based on priority group) and third-party insurance for non-service connected care and treatment of those Veterans who receive treatment related to the DePuy ASR™ Hip Resurfacing System replacement recall.

b. Although DePuy has noted in their press release that they will cover reasonable costs of treatment associated with the recall, that does not override the statutory requirement for billing. The Office of General Counsel will determine if VA should pursue reimbursement by litigation.

4. RESCISSION: None. This VHA Notice expires January 31, 2015.

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Under Secretary for Health

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