

## **Urgent Field Safety Notice (FSN)**

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**Product Name:** DePuy ReClaim® Reamer Extension

**FSCA-identifier:** DVA-107508-HHE

**Type of Action:** Field Safety Notice

**Date:** Oct 2014

**Attention:** Trust Chief Executives, the Clinical Director-Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers – Private Sector Hospitals

**Type of device:** Orthopaedic Hip Joint Replacement Instrument

**Model names:** DePuy ReClaim® Reamer Extension

In March 2013, DePuy Orthopaedics, Inc. issued a voluntary device correction for the RECLAIM® Distal Reamer Extension (2975-00-500) due to the potential for one or both of the tabs on the original design to break off and potentially be left in the patient. The RECLAIM® Distal Reamer Extension has been redesigned, and the company is formally swapping out the affected instruments.

#### **Affected RECLAIM Distal Reamer Extension Instrument (Figure 1):**

**Product Code:** 2975-00-500

**Lot Numbers:** See Attachment A



Figure 1: Affected RECLAIM Distal Reamer Extension (2975-00-500)

#### **Swap-Out Instrument Set**

The redesigned instruments include a RECLAIM Clear-Out Reamer (2976-20-000) and an updated RECLAIM Instrument Tray (2975-50-600), which will be included as part of the swap-out set.