Urgent Field Safety Notice (FSN)

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.