

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

**Product Name:** ADEPT® 12/14 Modular Head (Finsbury Orthopaedics Ltd)

**FSCA-identifier:** DVA-107259-HHE

**Type of Action:** Field Safety Corrective Action

**Date:** 15<sup>th</sup> January 2013

**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:** Total Hip Replacement Implant

**Model names:** ADEPT® 12/14 Modular Head (Finsbury Orthopaedics Ltd)

**Model number:** Reference Appendix A

**Batch / lot number of affected devices:** All lots

**Action:**

DePuy is issuing a field safety corrective action (FSCA) for all lots of the ADEPT® 12/14 Modular Head used in total hip arthroplasty. If you have any remaining inventory please cease further distribution or use of the product with immediate effect.

**Summary:**

Review of post-market surveillance data suggests a higher than expected revision rate for the ADEPT® 12/14 Modular Head (Finsbury Orthopaedics Ltd) when used in conventional Total Hip Arthroplasty.

The ADEPT® 12/14 Modular Head was manufactured by Finsbury Orthopaedics Ltd. Finsbury was acquired by DePuy in December 2009. ADEPT® 12/14 Modular Heads were available commercially from Finsbury or DePuy from 2004 to September 2011. From September 2011, ADEPT® 12/14 Modular Heads were acquired by MatOrtho Ltd.

**Note: This Field Safety Notice does not apply to ADEPT® Hip Resurfacing Femoral components.**

**Background:**

Analysis of UK National Joint Registry Supplier Feedback data (download 11<sup>th</sup> November 2012) indicates a cumulative revision rate of 12.1% (95% CI 9.5% to 15.4%) at 7 years for the ADEPT® 12/14 Modular Head when used in conventional Total Hip Arthroplasty. When this combination is used with the ADEPT® Cementless Stem, the data showed a cumulative revision rate of 9.7% (95% CI 5.9% to 15.5%) at five years. This is based on 17 revisions in a cohort of 195 implantations.

Whilst there are differences in the relative performance of particular stem combinations with the ADEPT® 12/14 Modular Head, and the cohort sizes for other head/stem combinations detailed below are small, the aggregate data shows a cumulative revision rate of 9.6% (95% CI 6.7% to 13.7%) at 5 years for approved ADEPT® 12/14 Modular Head - stem combinations. Data for all approved combinations is shown below.

This data suggests a higher than expected revision rate for the ADEPT® 12/14 Modular Head (Finsbury Orthopaedics Ltd) when used in conventional Total Hip Arthroplasty. Based on the aggregate data, we are initiating a FSCA on the ADEPT® 12/14 Modular Head (Finsbury Orthopaedics Ltd).

<b>Adept XL Type (Head/Stem)</b>	<b>Cumulative Revision Rate</b>	<b>No Implanted / No Revised</b>
Adept/Adept Cementless	9.65% (95% CI 5.93% to 15.51%) at 5 years	195 / 17
Adept/Corail	4.35% (95% CI 1.11% to 16.29%) at 2 years	46 / 5
Adept/Freeman Cemented Finsbury	Not Available due to small cohort	1 / 0
Adept/Freeman Cementless	2.44% (95% CI 0.35% to 16.08%) at 3 years	46 / 3
Adept/Finsbury Type C	2.08% (95% CI 0.30% to 13.88%) at 2 years	48 / 3
Adept/LPR	6.67% (95% CI 2.20% to 19.26%) at 2 years	45 / 4

The primary reasons for revision surgery are:

- Aseptic loosening of the stem
- Soft tissue reaction
- Pain

In September 2012, the Australian Orthopaedic Association National Joint Replacement Registry reported a cumulative revision rate of 7.1% (95% CI 3.6% to 13.6%) at 3 years with 8 revisions in a cohort

of 121 ADEPT® 12/14 Modular Head cases used in conventional Total Hip Arthroplasty. The on-label cohorts remain small with no revisions due to metal sensitivity (4 loosening/lysis, 2 infection, 1 prosthesis dislocation and 1 pain).

**Please undertake the following urgent actions:**

- Quarantine/Bond any **ADEPT® 12/14 Modular Head** inventory that is located at your facility or hospital.
- Arrange with your local DePuy representative to return for credit any unused implants
- Please sign and return the confirmation/reconciliation letter below to the specified DePuy contact.
- Please ensure all departments and colleagues within your organisation who are impacted by this Field Safety Corrective Action notification are made aware of this action.

**Patient Care:**

Patients who have received the ADEPT® 12/14 Modular Head should be followed according to local guidance/standard of care for patients receiving metal on metal (MoM) articulations. Please refer to your local orthopaedic association for detailed information related to the treatment of patients with metal-on-metal articulations.

**Transmission of this Field Safety Notice:**

This notice has been sent to you as records indicate that your organisation has purchased the ADEPT® Modular Head.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where these products may have been transferred.

**For any enquiries regarding the ADEPT® System (Finsbury Orthopaedics Ltd):**

**Contact**

Alan O' Sullivan (DePuy)

Recall Coordinator

e-mail – [aosulliv@its.jnj.com](mailto:aosulliv@its.jnj.com)

Tel no - +353 21 4914149



This FSN has been notified to the appropriate Regulatory Agency.

Date: 15-Jan-2013

**This Letter acknowledges receipt of the Field Safety Notice [ref. DVA-107259-HHE] dated [INSERT DATE] issued by DePuy Orthopaedics.**

We have checked our current inventory:

(Please check as appropriate)

No ADEPT® 12/14 Modular Head(s) are located at our facility.

**or**

The products listed below are in our inventory and will be returned to DePuy Orthopaedics or a representative of DePuy. (Add rows as required)

Please fax or e-mail this completed document to [INSERT DePuy Marketing Company/Affiliate contact details]

Part Number	LOT/Batch Number	Quantity

Print Name: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Hospital Name

\_\_\_\_\_  
Country

\_\_\_\_\_  
City, State, Post Code/Zip

\_\_\_\_\_  
Telephone Number or e-mail address

**Note: When returning inventory please ensure this letter accompanies any returns**

**Appendix A**

**ADEPT® 12/14 Modular Head**

<b>Product Code DePuy</b>	<b>Product Code Finsbury</b>	<b>Description</b>
180238F	180238	ADEPT® 12/14 MoM Mod Head 38 mm -3.5 mm Neck
180240F	180240	ADEPT® 12/14 MoM Mod Head 40 mm -3.5 mm Neck
180242F	180242	ADEPT® 12/14 MoM Mod Head 42 mm -3.5 mm Neck
180244F	180244	ADEPT® 12/14 MoM Mod Head 44 mm -3.5 mm Neck
180246F	180246	ADEPT® 12/14 MoM Mod Head 46 mm -3.5 mm Neck
180248F	180248	ADEPT® 12/14 MoM Mod Head 48 mm -3.5 mm Neck
180250F	180250	ADEPT® 12/14 MoM Mod Head 50 mm -3.5 mm Neck
180252F	180252	ADEPT® 12/14 MoM Mod Head 52 mm -3.5 mm Neck
180254F	180254	ADEPT® 12/14 MoM Mod Head 54 mm -3.5 mm Neck
180256F	180256	ADEPT® 12/14 MoM Mod Head 56 mm -3.5 mm Neck
180258F	180258	ADEPT® 12/14 MoM Mod Head 58 mm -3.5 mm Neck
180338F	180338	ADEPT® 12/14 MoM Mod Head 38 mm +0 mm Neck
180340F	180340	ADEPT® 12/14 MoM Mod Head 40 mm +0 mm Neck
180342F	180342	ADEPT® 12/14 MoM Mod Head 42 mm +0 mm Neck
180344F	180344	ADEPT® 12/14 MoM Mod Head 44 mm +0 mm Neck
180346F	180346	ADEPT® 12/14 MoM Mod Head 46 mm +0 mm Neck
180348F	180348	ADEPT® 12/14 MoM Mod Head 48 mm +0 mm Neck
180350F	180350	ADEPT® 12/14 MoM Mod Head 50 mm +0 mm Neck
180352F	180352	ADEPT® 12/14 MoM Mod Head 52 mm +0 mm Neck
180354F	180354	ADEPT® 12/14 MoM Mod Head 54 mm +0 mm Neck
180356F	180356	ADEPT® 12/14 MoM Mod Head 56 mm +0 mm Neck
180358F	180358	ADEPT® 12/14 MoM Mod Head 58 mm +0 mm Neck
180438F	180438	ADEPT® 12/14 MoM Mod Head 38 mm +3.5 mm Neck
180440F	180440	ADEPT® 12/14 MoM Mod Head 40 mm +3.5 mm Neck
180442F	180442	ADEPT® 12/14 MoM Mod Head 42 mm +3.5 mm Neck
180444F	180444	ADEPT® 12/14 MoM Mod Head 44 mm +3.5 mm Neck
180446F	180446	ADEPT® 12/14 MoM Mod Head 46 mm +3.5 mm Neck
180448F	180448	ADEPT® 12/14 MoM Mod Head 48 mm +3.5 mm Neck
180450F	180450	ADEPT® 12/14 MoM Mod Head 50 mm +3.5 mm Neck
180452F	180452	ADEPT® 12/14 MoM Mod Head 52 mm +3.5 mm Neck
180454F	180454	ADEPT® 12/14 MoM Mod Head 54 mm +3.5 mm Neck
180456F	180456	ADEPT® 12/14 MoM Mod Head 56 mm +3.5 mm Neck
180458F	180458	ADEPT® 12/14 MoM Mod Head 58 mm +3.5 mm Neck
180538F	180538	ADEPT® 12/14 MoM Mod Head 38 mm +7 mm Neck
180540F	180540	ADEPT® 12/14 MoM Mod Head 40 mm +7 mm Neck
180542F	180542	ADEPT® 12/14 MoM Mod Head 42 mm +7 mm Neck
180544F	180544	ADEPT® 12/14 MoM Mod Head 44 mm +7 mm Neck

180546F	180546	ADEPT® 12/14 MoM Mod Head 46 mm +7 mm Neck
180548F	180548	ADEPT® 12/14 MoM Mod Head 48 mm +7 mm Neck
180550F	180550	ADEPT® 12/14 MoM Mod Head 50 mm +7 mm Neck
180552F	180552	ADEPT® 12/14 MoM Mod Head 52 mm +7 mm Neck
180554F	180554	ADEPT® 12/14 MoM Mod Head 54 mm +7 mm Neck
180556F	180556	ADEPT® 12/14 MoM Mod Head 56 mm +7 mm Neck
180558F	180558	ADEPT® 12/14 Metal on Metal Modular Head 58mm +7mm Neck