



رقم المحفوظات: ١١/٢٨
رقم الصادر: ١٣/١١/٦١٨٧
بيروت، في: ١٥ شباط ٢٠١٣

جانب شركة Asmar Medical

الموضوع: إشعار بمتابعة جهاز طبي
Prostheses, Joint, Hip, Femoral Component

الجهاز المعنى بالمتابعة:

- Prostheses, Joint, Hip, Femoral Component (Model names: DePuy G2, FJORD, UITIMA TPS, Eurometric and FREEMAN)
- Trade Mark: DePuy International Limited
- Local Representative: Asmar Medical

بناء على التوصية الصادرة عن الشركة المصنعة التي تشير الى مضاعفات جراء استعمال الصنف المذكور أعلاه ، نرجو منكم تعميم طريقة الاستعمال الصادرة عن الشركة لجهة استعمال هذا الصنف مع (Ultima Metal-on-Metal)

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- ✓ دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

د. وليد عمار
مدير عام الصحة
وزارة الصحة العامة
الجمهورية اللبنانية



Field Safety Notice (FSN)

Product Name: DePuy G2, FJORD, ULTIMA TPS, EUROMETRIC and FREEMAN Cemented Femoral Hip Stems (Germany)

FSCA-identifier: DVA106196

Type of Action: Field Safety Notice

Date: 16 April 2012

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 – Cemented, Polished¹, Cobalt Chromium Alloy (CoCr) Femoral Hip Stems in Combination with Metal-on-Metal (MoM) Articulations².

Model names: DePuy G2, FJORD, ULTIMA TPS, EUROMETRIC and FREEMAN Cemented Femoral Hip Stems

Model number: Reference Appendix A

Batch / lot number of affected devices: All lots

Important Announcement:

A UK Medicines and Healthcare products Regulatory Agency (MHRA) Medical Device Alert, MDA/2007/054, was issued on the 14th June 2007, as a consequence of DePuy issuing a 'Dear Dr. Letter' in February 2007 to Ultima TPS users in the UK, to communicate that one UK study centre had reported 43 revisions (from a cohort of 637 hips) of the polished CoCr DePuy ULTIMA TPS total hip replacement femoral stems. These revisions were associated with extensive peri-prosthetic soft tissue necrosis. In all cases the femoral hip stem was implanted in combination with the ULTIMA Metal-on-Metal. When these stems were explanted, extensive corrosion was observed on the polished surface within the area of the cement mantle (i.e. the area of the stem in contact with the bone cement).

Since the above alert was circulated, DePuy has continued to carry out post market surveillance activities and research into this issue. DePuy has become aware of two reports of corrosion at a second facility in the UK involving the ULTIMA TPS cemented polished CoCr hip stem used with a MoM articulation². DePuy's post market surveillance data sources have not identified any adverse events related to corrosion of the G2, FJORD, EUROMETRIC and FREEMAN stems. However, research has led DePuy to conclude that, when used in combination with a MoM articulation² DePuy's cemented, polished¹, CoCr femoral hip stems, including the G2, FJORD, ULTIMA TPS, EUROMETRIC and FREEMAN stems could potentially exhibit excessive corrosion



of the polished surfaces which are within the cement mantle. This corrosion could potentially lead to an increased incidence of peri-prosthetic soft tissue necrosis.

Therefore, DePuy is issuing a Field Safety Notice to advise against the implantation of the following configuration: **DePuy's cemented, polished, CoCr alloy femoral hip stems combined with MoM articulation².**

In addition DePuy has decided to amend the Instructions for Use (IFU) product labeling for the G2 hip stems. The new IFU will include a warning against implantation of these specific hip stems combined with a metal-on-metal articulation². The IFU product labeling for the following products will not be updated as these products are now obsolete: FJORD, EUROMETRIC, ULTIMA TPS and FREEMAN

The femoral stems which have been available in your country to which this Field Safety Notice applies are the DePuy FJORD (distributed from 1997 until May 2011) FREEMAN (distributed from 2004 until July 2011) EUROMETRIC (distributed from 2003 until Sept 2011) ULTIMA TPS (distributed from 1996 until 2009) and G2 (distributed from September 1998) cemented, polished, CoCr stems (product codes as listed within Appendix A) when combined with a MoM articulation².

Clinical Implications

The possible clinical implications related to the implantation of the DePuy G2, FJORD, ULTIMA TPS, EUROMETRIC and FREEMAN cemented, polished, CoCr alloy femoral hip stems combined with a MoM articulation² include excessive corrosion within the cement mantle that could lead to an adverse tissue reaction and/or soft tissue damage which may lead to a revision surgery. If a revision surgery is required, the following are general examples of possible risks/hazards that can result:

1. Infection (Post-operative initial and revision surgery, intra-operative revision surgery.)
2. Additional scarring (Post-operative revision surgery.)
3. Neural and vascular damage (Intra-operative revision surgery.)
4. Additional pain to the patient. (Post-operative initial and revision surgery.)
5. Low probability of improper alignment of the implant. (Post-operative initial and revision surgery, intra-operative revision surgery.)
6. Functional problems resulting from items 1 – 5 above. (Post-operative initial surgery and post-operative revision surgery.)
7. Anesthesia associated risks as a result of the additional surgery. (Intra-operative revision surgery.)

NOTE: DePuy's research has not led DePuy to conclude that the DePuy G2, FJORD, EUROMETRIC and FREEMAN Hip Stems when used in any other combination, could potentially exhibit excessive corrosion of the polished surfaces which are within the cement mantle.



Patient Care:

Patients should be followed according to local guidance/standard of care for patients receiving a MoM articulation. Please refer to your local orthopaedic association for detailed information related to the treatment of patients with a MoM articulation.

Transmission of this Field Safety Notice:

This notice has been sent to you as our records indicate that your organisation has purchased the G2, FJORD, ULTIMA TPS, EUROMETRIC or FREEMAN hip stems.

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.

Contact:

Alan O'Sullivan
Recall Coordinator
DePuy (Ireland)
Loughbeg
Ringaskiddy
Co. Cork
Ireland

Tel: +353 21 4914149

This FSN has been notified to the appropriate Regulatory Agency.



Date: 16 April 2012

Alan O'Sullivan
Recall Coordinator

Notes:

1. *Within the cement contact area.*
2. *Including a head of CoCr and an acetabular cup where the cup is of an all metal construction (monoblock or modular).*