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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

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بيروت، في: ٢٠ ايار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعني بالمتابعة:

- Joint prosthesis, shoulder, Glenoid component
  Trade Mark: Lima Orthopaedics
  Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في عمل الجهاز المذكور أعلاه والذي قد يؤدي الى مضاعفات على المريض، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

مرفق ربطاً:
- التوصية الصادرة عن الشركة المصنعة.

يبلغ:
- دائرة البرامج والمشاريع
- الموقع الالكتروني لوزارة الصحة
- المحفوظات

مدير عام الصحة
د. وليد عمار

وثيقة مصدقة للأصل
بيروت في ٢١ ايار ٢٠١٢
رئيس قسم امانة السر
عناية غصن

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Date 23rd August 2012

Topic : Lima SMR Anatomical Polythylene Liner

Dear Mr XXXXXXXXX

Our colleagues in Lima Australia have recently analysed the performance of their SMR total anatomical shoulders and found that the most recent used polyethylene anatomical liner (L2) has had a higher rate of disassociation from the metal back than the prior version (L1). They have therefore moved their surgeons back to the previous L1 design for anatomical shoulders. In the UK we have not seen this increased rate of disassociation but as a precautionary measure will provide the L1 design of anatomical liner and corresponding metal back ongoing. We are also contacting all surgeons who have implanted an L2 liner and metal back to inform them of this Australian situation.

Published clinical results of the L1, including those in the Australian and New Zealand Joint registries, demonstrate the successful long-term stability of the SMR metal back baseplate and the utility of being able to convert an anatomic total shoulder to a reverse to manage patients with subsequent shoulder instability or cuff failure without requiring the destructive removal of well fixed humeral and metal glenoidcomponents[1,2,3,4,5].

The L1 version of the metal back was launched in 2002 and designed to be used for either anatomic or reverse total shoulder replacement. Worldwide, 2900 of these have been implanted in anatomic shoulder replacement.

L1 Design Metal Back Glenoid

In 2009, Lima made changes to the baseplate design, removing the metal lugs and manufacturing the insert from cross-linked polyethylene (L2 Version) Worldwide, 2,277 of these have been implanted in anatomic shoulder replacement.

L2 Design of Metal Back Glenoid

Patients who have received an L2 version of the SMR metal back glenoid and poly liner should be followed up according to routine protocol. Liner disassociation has most often been associated with a traumatic event, sport or exercise, or failure of the rotator cuff. Patients should be reminded at follow up that strenuous exercise or sporting activities could impact the longevity of their joint replacement. In a situation where liner disassociation has occurred, patients may present with pain, limited range of motion and they may complain of a 'squeaking', 'clicking' or 'grinding' sensation.

If you have any further queries please do not hesitate to contact myself or your local WG / Lima UK sales person.

Kind Regards

Paul Gibbons

Marketing Manager
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References:
1. A Castagna et al, JBJS Br 2010:
35 Cases, 74 months average follow up with no Metal back loosening, no liner disassociations, no implant related complications
2. K Mohammed, JBJS 2012 Br Supp XXI: 192 Cases, minimum follow up 36 months (longest follow up 60 months), "6/192 metal back cases had a revision procedure, but none were for the glenoid component"
3. K Mohammed et al, JBJS 2012 Br Supp XXI: 20 cases, 45 months average follow up, "No components were loose. All components were osteointegrated around the central peg"
4. Australian Orthopaedic Association National Joint Replacement Registry, Annual Report. Adelaide: AOA;2009
5. The New Zealand Joint Registry 2009