جانب نقيب الاطباء في لبنان/بيروت

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 والتصويت الصادرة عن الشركة المصنعة والتي تفيد بوجود خلال أثناء استعمال الصفّ المذكور أعلاه والذي يؤدي الى مضاعفات على المريض، نرجو منكم متابعة هذا الموضوع مع الأطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

موفق ريطا:
التصويت الصادرة عن الشركة المصنعة.

بلاغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفظات
الموضوع: إشعار بمتابعة جهاز طبيعي مغروس

الجهاز المعني بالمنطقة:
- 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

والتصويب الصادرة عن الشركة المصنعة والتي تفيد بوجود خلال أثناء استعمال الصنف
المذكور أعلاه والذي يؤدي إلى مضاعفات على المريض، نرجو منكم تعميم هذه النشرة على
المستشفى المعني.

مرفق ربط:
- التوصية الصادرة عن الشركة المصنعة.

بلاغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المفتوحات
الموضوع: إشعار بمتابعة جهاز طبي مغروس

- 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

والتصويت الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل أثناء استعمال الصنف
المذكور أعلاه والذي يؤدي إلى مضاعفات على المريض، نرجو منكم متابعة هذا الموضوع مع
الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربط:
- التوصية الصادرة عن الشركة المصنعة.
  بلغ:
  - دائرة البرامج والمشاريع
  - المستشفيات الحكومية
  - المحفوظات

مدير على الصحة
ليد حسن
URGENT FIELD SAFETY NOTICE

Product name: L2 poly liner for metal back glenoid, SMR Shoulder System
Related FSCA no.: NC 1758/12
Action type: spontaneous recall of medical device
Date: 27th September 2012

To the kind attention of: Health Directors; Orthopaedic Head Physicians; Orthopaedic Surgeons; Vigilance Directors; Chief Executive Officers (only for Private Facilities)

Product codes: 1377.51.050, 1377.51.060, 1377.51.070, 1377.51.080
Device type: implantable device for SMR Anatomic prosthesis
Batch number: all
Notes: N/A

Problem description
Close monitoring and analysis of the early clinical results of SMR total anatomic shoulder replacements performed with the L2 glenoid liner indicate that, under certain conditions, for example rotator cuff failure or patient trauma, the liner may disassociate from the metal back baseplate.

In most of the cases the problems do not seem to be strictly product related, nevertheless – for the Australian and New Zealand markets – Limacorporate decided to discontinue the L2 reintroducing the L1 liners. The published clinical results of the L1 glenoid system, including those in the Australian and New Zealand Joint registries, demonstrate the successful long-term stability of the SMR metal back baseplate. Both the L1 and L2 baseplates have been demonstrating successful in converting 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 glenoid components.1,2,3,4,5

Even if in the European market the rate of dissociations is significantly lower than in the Australian one, as a precautionary marketing measure, Limacorporate is going to discontinue the L2 liners and to reintroduce the L1 System (liners and metal back baseplate).
URGENT FIELD SAFETY NOTICE

baseplates) in the European market too, in order to grant surgeons the most precautionary choice for the total anatomic shoulder replacement.

Table 1, below, shows the codes of the L1 liners and the correspondent metal back baseplates for the 4 sizes available (Small-R, Small, Standard, Large).

<table>
<thead>
<tr>
<th>L1 liner codes and sizes</th>
<th>L1 metal back baseplate codes and sizes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1377.50.005, # Small-R</td>
<td>1375.20.005, # Small-R</td>
</tr>
<tr>
<td>1377.50.020, # Small</td>
<td>1375.20.020, # Small</td>
</tr>
<tr>
<td>1377.50.010, # Standard</td>
<td>1375.20.010, # Standard</td>
</tr>
<tr>
<td>1377.50.030, # Large</td>
<td>1375.20.030, # Large</td>
</tr>
</tbody>
</table>

Table 1: L1 liner and metal back baseplate codes and sizes.

NOTE: in case of total reverse shoulder replacement, surgeons might safely use the L2 metal back with the SMR glenospheres. Primary partial shoulder replacement or total anatomic shoulder replacement with cemented glenoids are not affected by this precautionary measure.

The following Table shows the codes of the L2 polyethylene liners which are object of this recall. All batch numbers for each code are involved.

<table>
<thead>
<tr>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>1377.51.050</td>
</tr>
<tr>
<td>1377.51.060</td>
</tr>
<tr>
<td>1377.51.070</td>
</tr>
<tr>
<td>1377.51.080</td>
</tr>
</tbody>
</table>

Table 2: L2 codes involved in the recall.

Surgeon information

Patients who have received an L2 version of the SMR 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, during the 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 feel pain, suffer limited range of motion and they may complain of a ‘clicking’ or ‘grinding’ sensation.
URGENT FIELD SAFETY NOTICE

X-Rays on the scapular plane will show a reduction in the joint space between the humeral head and the glenoid compared to the immediate post-operative X-Rays. These cases will require a revision and, basing on the clinical case (e.g.: deterioration of the soft tissue, rotator cuff failure) and on the best available medical technique and experience, the surgeon may consider the following options:

- conversion to an SMR Reverse prosthesis;
- revision to an L1 (for metal back baseplate and liner) glenoid system or to a cemented glenoid.

In any case a new humeral head or glenosphere should be implanted.

For any clarification needed or for the availability of the L1 System, you may refer to your usual customer contact.

Actions to be taken

We kindly ask you to return all the liners belonging to the codes specified in Table 2; we also ask you to fill in the attached response, by specifying the quantities to be returned for each code.

The products returned will be replaced by Limacorporate in the shortest time possible.

Dissemination of this FSN

This notice needs to be passed on all those who need to be aware within Your organization, or to any organization where the potentially affected devices have been transferred.

Contact name

Dr. Ing. Giulio Puppa
Post Market Surveillance

e-mail: giulio.puppa@limacorporate.com
fax: +39 0432 945512

c/o:
Limacorporate S.p.A.
Via Nazionale n.52
33038 Villanova di S. Daniele del Friuli
(UD)
URGENT FIELD SAFETY NOTICE

This Field Safety Notice will be submitted to the National Competent Authorities.

Quality and Regulatory Executive
Gabriele Calligaro

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"
5. The New Zealand Joint Registry 2009.