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MINISTÈRE DE LA SANTÉ PUBLIQUE
LE DIRECTEUR GÉNÉRAL

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٩/٢٥
رقم الصادر: ١٢/٧/١٨٢٤٤
بيروت، في: ٦ تشرين الثاني ٢٠١٢

جانب نقيب الاطباء في لبنان/بيروت

الموضوع: إشعار بمتابعة جهاز طبي مغروس Joint prosthesis, shoulder.

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 أثناء استعمال الصنف المذكور أعلاه والذي يؤدي الى مضاعفات على المريض ، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

المدير العام للصحة
د. وليد عمار

وثيقة مطابقة للأصل
بيروت في ٧ تشرين الثاني ٢٠١٢
رئيس قسم الدروس والتفاعلات الصحية والدولية
عيد ضومط

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الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٣٧/١/ص

رقم الصادر: ٤٤٤ص/١٨/١/١٢

بيروت، في : ٢ تشرين الثاني ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس Joint prosthesis, shoulder.

الجهاز المعني بالمتابعة:
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مرفق ربطاً:

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مدير عام الصحة

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الجمهورية اللبنانية
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رقم المحفوظات: ٣٨/ ٢٥
رقم الصادر: ١٧/١/١٨٣٤٤
بيروت، في: ٦ تشرين الثاني ٢٠١٢

جانب نقيب الاطباء في الشمال/طرابلس

الموضوع: إشعار بمتابعة جهاز طبي مغروس Joint prosthesis, shoulder.

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

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مرفق ربطاً:

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يبلغ:

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مدير عام الصحة
د. وليد عمار

Lima Corporate
Orthopaedic motion

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

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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).

L1 liner codes and sizes	*L1 metal back baseplate codes and sizes*
1377.50.005, # Small-R	1375.20.005, # Small-R
1377.50.020, # Small	1375.20.020, # Small
1377.50.010, # Standard	1375.20.010, # Standard
1377.50.030, # Large	1375.20.030, # Large

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.

Code
1377.51.050
1377.51.060
1377.51.070
1377.51.080

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.

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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 retuned 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)

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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"
4. Australian Orthopaedic Association National Joint Replacement Registry, Annual Report. Adelaide: AOA;2009;
5. The New Zealand Joint Registry 2009.

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