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From: [redacted]
Sent: Wednesday, 12 September 2012 4:04 PM
To: [redacted]
Cc:
Subject: SMR Anatomical Shoulder Prosthesis - New material for consideration prior to 6 pm Monday 17 Septemeber [SEC=UNCLASSIFIED]

Dear [redacted]

My apologies: It slipped my mind that there has recently been a "recall" of one type of glenoid component in the SMR shoulder range and that this may be relevant to your considerations on Monday 17 September.

As it has been explained to the TGA, the SMR anatomical shoulder can be used with either an "L1" glenoid component and liner or an "L2" glenoid component and liner. They differ in the way that the polyethylene liner is held in place. The "L2" glenoid and liner was introduced in response to a concern that the polyethylene of the "L1" could wear down to the glenoid component lugs that hold the liner in place and cause metal on metal wear. According to the manufacturer, the concern is not substantiated, but they produced the "L2" modification as a way of addressing surgeon demand.

According to Lima, the incidence of dissociation leading to revision for the L2 glenoid is much higher that that of the L1 glenoid. Therefore they have decided to discontinue the supply of the L2 glenoid and liner.

One of the matters for your consideration is whether the SMR revision rate is unacceptably high. If the manufacturer is correct, then their action should reduce the incidence of early SMR revisions due to dissociation dramatically.

I have attached information supplied to the TGA by Lima Orthopaedics for your consideration before Monday.

I am looking forward to our meeting

Regards

[redacted]
A/g Head - Office of Laboratories and Scientific Services
Therapeutic Goods Administration

✉ : PO Box 100, Woden, ACT 2606, Australia

☎: [redacted]

Draft - Product Notification ...

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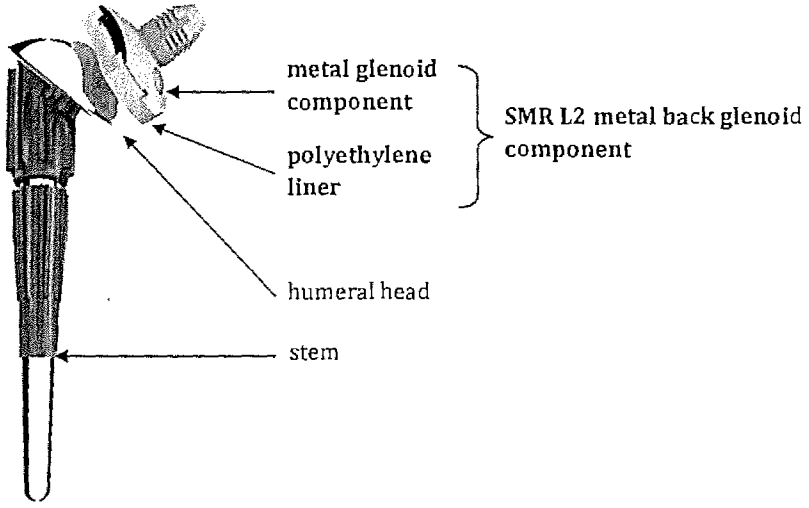
SMR L2 Metal Back Glenoid Component (used in shoulder replacements)—product discontinued

The Shoulder Modular Replacement (SMR), sponsored by Lima Orthopaedics Australia, is an implant used in shoulder replacements. It consists of a metal glenoid component, a polyethylene liner, a humeral head and a stem.

The metal glenoid component and polyethylene liner together comprise the SMR L2 Metal Back Glenoid Component (see diagram below).



The TGA advises health professionals and patients that the SMR L2 Metal Back Glenoid Component has been discontinued. Data collected by the Australian National Joint Replacement Registry (NJRR) revealed that the SMR had a higher than expected revision rate. The TGA contacted Lima Orthopaedics Australia, whose subsequent investigations revealed that under certain conditions, for example: rotator cuff failure or patient trauma, the SM L2 Metal Back Glenoid Component's polyethylene liner could become detached from the glenoid component, and that this had increased the revision rate of the SMR. As a result, the SMR L2 Metal Back Glenoid Component has been discontinued.

Comment [redacted] Please add hover text definition

The L2 was introduced in 2009 in response to concerns that the polyethylene liner in the L1 version could wear down and lead to metal-on-metal contact. Subsequently, very few cases of polyethylene wear have actually been observed with the L1 design.

The TGA's routine processes involve close analysis of NJRR annual reports, together with review of internal incident reports and consideration of external specialist advice.

Information for consumers

Liner disassociation is most often linked to sport or exercise, a traumatic event, or failure of the rotator cuff. Patients are reminded that strenuous exercise or sporting activity can impact the longevity of a joint replacement.

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Contact your general practitioner/surgeon if you experience any of the following at the site of your shoulder replacement:

- pain
- limited range of motion
- a 'squeaking', 'clicking' or 'grinding' sensation.

Each patient's circumstances are different and the TGA cannot give individual clinical advice regarding the SMR L2 Metal Back Glenoid Component.

Information for orthopaedic surgeons

Given the nature of the problem, there is no urgent need to contact patients who have received an L2 version of the SMR Metal Back Glenoid Component. However, it is recommended that those patients be followed up according to their routine protocol and advised of this issue at that stage.

If a patient presents with pain, a limited range of motion and/or complaining of a 'squeaking', 'clicking' or 'grinding' sensation at the site of their shoulder replacement, assess the component and follow your established protocols.

Lima Orthopaedics Australia has sent a hazard alert regarding the disassociation risk to all surgeons who have used this shoulder replacement system.

Information for all health professionals

Patients with any shoulder replacement should be followed up by the implanting orthopaedic surgeon if possible, particularly if the patient complains of pain, limited range of motion, or a 'squeaking', 'clicking' or 'grinding' sensation associated with their shoulder implant and surgery.

Technical information

The TGA monitors the safety and performance of orthopaedic implants using data collected by the NJRR since 2006. This and other recent hazard alerts relating to hip replacement implants have arisen from the TGA's routine processes involving close

analysis of the NJRR annual reports, together with review of internal incident reports and consideration of external specialist advice.

The annual reports of the NJRR and detailed information about implants that were identified as having higher than expected revision rates going back a number of years are available the NJRR website.

Lima Orthopaedics Australia has monitored the performance of the L2 component since introduction and has found that the total revision rate of the component in Australia is 6.78% at 3 years.

Based on these findings, Lima Orthopaedics Australia is of the view that the L2 liner is not performing as well as the original L1. As a result, only L1 components have been available since 6 August 2012.

Reporting problems

Patients and health professionals are encouraged to report problems with medical devices. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS).

The TGA cannot give personal advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.