Fw: Web publishing request - Four joint implant web statements [DLM=For-Official-Use-Only]

[redacted] to: recalls 31/10/2012 09:31 AM

From: [redacted]
To: recalls@tga.gov.au

Please include the appropriate final web statements (click on the link below) in each file .

Best regards,

[redacted] Recalls & Advertising Unit I Office of Product Review I Monitoring & Compliance Group I Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 I www.tga.gov.au
T: [redacted] Recalls@tga.gov.au

TGA Health Safety Regulation [redacted]

----- Forwarded by [redacted] TGA/Health on 31/10/2012 09:29 AM -----

From: TGA WEBSITE
To: [redacted]
Cc: [redacted]

Date: 30/10/2012 05:32 PM
Subject: Re: Web publishing request - Four joint implant web statements [DLM=For-Official-Use-Only]
Sent by: [redacted]

Hi,

The following four web statements are live on the TGA website:

SMR L2 Metal Back Glenoid Component (used in shoulder replacements)
Durom Acetabular Component (used in hip replacements)
Birmingham Hip Modular Head (used in hip replacements)
Apex K2 Femoral Stem (used in hip replacements)

Regards,

[redacted]

From: [redacted]
To: TGA WEBSITE@TTRA
Cc: [redacted]

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

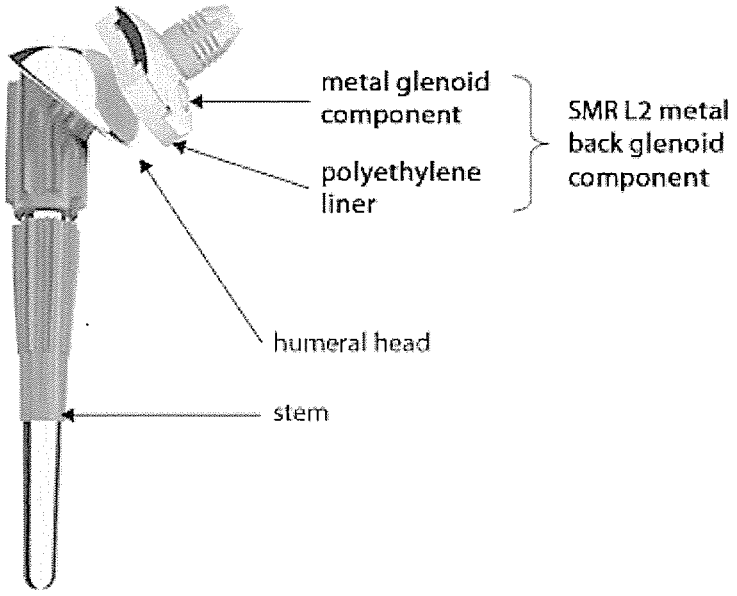
SMR L2 Metal Back Glenoid Component (used in shoulder replacements)

Product discontinued

30 October 2012

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.

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.

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.

Content last updated: Tuesday, 30 October 2012

Web page last updated: Wednesday, 31 October 2012

URL: http://www.tga.gov.au/safety/alerts-device-shoulder-smr-121030.htm