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

[redacted] to: recalls 30/10/2012 12:05 PM

Can you print and include the appropriate documents 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] on 30/10/2012 12:04 PM -----

From: [redacted]
To: TGA WEBSITE@TTRA
Cc: [redacted] News@health.gov.au, #TGA Executive, gsupc@tga.gov.au
Date: 29/10/2012 04:43 PM
Subject: Web publishing request - Four joint implant web statements [DLM=For-Official-Use-Only]

TGA website

Approval under subsection 61 (7) of the Therapeutic Goods Act 1989
Under subsection 61(7) of the Therapeutic Goods Act 1989, the delegate of the Secretary may release to the public therapeutic goods information where release is necessary to ensure the safe use of particular therapeutic goods or relating to the reasons for withdrawal of therapeutic goods from supply.

In relation to issues with the Apex K2 Modular Hip Replacement System, the Durom Acetabular Component, The Birmingham Hip Modular Head (BHR), and the SMR L2 Metal Back Glenoid Component I, as delegate of the Secretary for the purposes of section 61 of the Act, approve under section 61(7) of the Act the release to the public of the therapeutic goods information relating to these actions as set out below.

Also below are the hover text requests.

Noting the size of this can you estimate when they might go up on the TGA website noting they do not need to go up today!

Thanks

[redacted] TGA Executive | Therapeutic Goods Administration | PO Box 100, WODEN ACT 2606 | Ph: [redacted] | Fax: [redacted] Mob: [redacted] Email: [redacted]

Also, here are the hover text definitions requested:

Total conventional hip replacement: A procedure in which the femoral head (the 'ball' part of the thigh bone) is replaced with an implant that has a stem going down inside the thigh bone. A matching cup is placed in the acetabulum (the 'socket' part of the joint).

Resurfacing hip replacement :A procedure in which only the surface of the femoral head (the 'ball' part of the thigh bone) is removed and a hollow cap is placed over it. A matching cup is placed in the acetabulum (the 'socket' part of the joint).

Lysis: Bone loss.

Rotator cuff: The group of muscles and tendons that stabilise and control rotation of the shoulder.

[redacted]
Office of Product Review
Monitoring and Compliance Group

Phone: [redacted]
Mobile: [redacted]
Fax: [redacted]
Email: [redacted]

Therapeutic Goods Administration

120

Department of Health and Ageing
PO Box 100
Woden ACT 2606
www.tga.gov.au

[redacted]

From: [redacted]
To: [redacted]
Date: 29/10/2012 03:17 PM
Subject: RE: Web publishing request - Four joint implant web statements [DLM=For-Official-Use-Only]

[redacted]
Can you send me the 4 web statements as both TRIM links and as word documents so when I send it to TGA website I can inform the CMO and Kay
Thanks
[redacted]

[redacted]
Therapeutic Goods Administration
Department of Health and Ageing

Tel: [redacted]
Fax:
Mob
E-mail: [redacted]
From IPad

-------- Original Message --------

From : [redacted]
To : [redacted]
Cc : [redacted]
Sent on : 29/10/2012 03:07:12 PM
Subject : Fw: Web publishing request - Four joint implant web statements [DLM=For-Official-Use-Only]

Hi [redacted]

Further to our earlier correspondence, I have set up the web publishing request (see below).

When you are ready to sign off, could you please forward the documents to tga.website@tga.gov.au indicating your approval.

Thank you,

[redacted]

[redacted]
Office of Product Review
Monitoring and Compliance Group

Phone: [redacted]
Mobile: [redacted]
Fax: [redacted]
Email: [redacted]

Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
www.tga.gov.au

[redacted]
----- Forwarded by [redacted] on 29/10/2012 03:05 PM -----

From: <tga.website@tga.gov.au>
To: [redacted]
Date: 29/10/2012 03:04 PM
Subject: Web publishing request - Four joint implant web statements

TGA web publishing request

Thank you for submitting a web publishing request form. Please forward this email to the clearance officer nominated in the form, and ask this officer to forward the final version to tga.website@tga.gov.au indicating their approval.

If you have any questions, please contact TGA website by email or by calling (02) 6232 8509.

Job details	
Internet or TGAnet update:	Internet
Job type:	New content
Job description:	Please find attached four web statements on joint implants (three hip implants and one for shoulders) to be published on the TGA website in the Alerts section.
Publish date:	Standard timeframe
Primary audience:	Consumers Health professionals
Show in What's New?	Yes
Contact person	
Contact name:	[redacted]
Contact email:	
Area:	Monitoring and Compliance Group
Office:	Office of Product Review
Section:	Management and Coordination (OPR)
Contact telephone:	[redacted]
Approval	
Approving officer:	[redacted]

Other comments

Web statement - Apex K2 Modular Hip Replacement System.DOCX

TRIM Link - Web statement - Apex K2 Modular Hip Replacement System.tr5

Web statement - Durom Acetabular Component.DOCX

TRIM Link - Web statement - Durom Acetabular Component.tr5 Web statement - BHR.DOCX

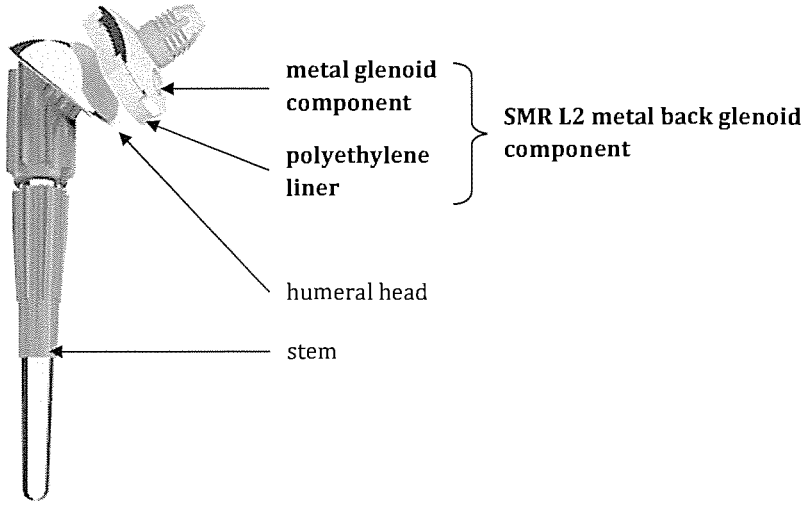
TRIM Link - Web statement - BHR.tr5 Web statement - SMR L2 Metal Back Glenoid Component.DOCX

TRIM Link - Web statement - SMR L2 Metal Back Glenoid Component.tr5

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.

Comment [redacted] Please add hover text definition

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

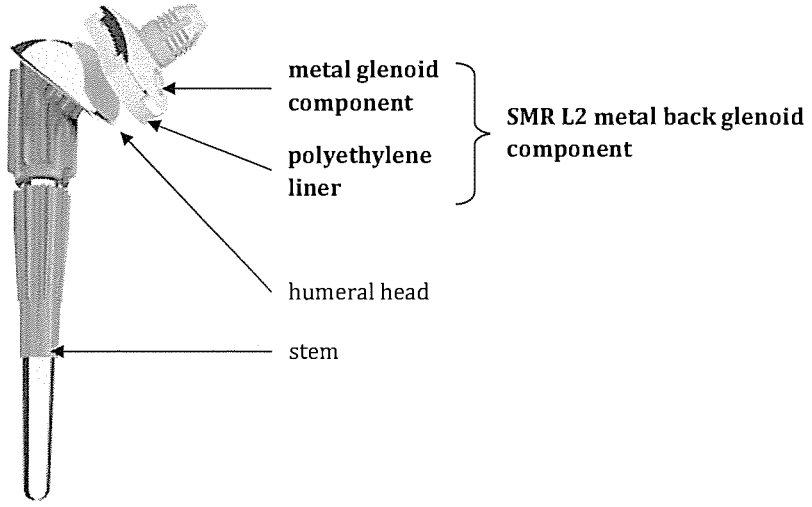
Patients and health professionals are encouraged to report problems with medical devices. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS).

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.

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.

Comment [redacted]: Please add hover text definition

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.