

INITIAL ASSESSMENT FORM – RECALLS AND NON RECALL ACTIONS

RECALLS REFERENCE NUMBER NotificationKey

PRODUCT name:	SMR L2 Metal Back Glenoid Component (Part of the Total shoulder Replacement)
ARTG Number(s):	
Sponsor/Supplier:	Lima Orthopaedics Australia Pty Ltd
Approval Area:	MEDDEV

PROBLEM Description	Monitoring and analysis of the clinical results of the SMR L2 Metal Back Glenoid Component indicate that under certain conditions, for example rotator cuff failure or patient trauma, the polyethylene insert can disassociate.
Product Affected:	See above
Distribution of affected product:	To be submitted

Hazard Category:	Class II
Hazard description:	In a situation where liner dissociation has occurred, patient may present with pain, limited range of motion. Diagnostic images will show a reduction in the joint space between the humeral head and the glenoid compared to the immediate post-operative diagnostic images. For more information , please see the SMR Metal Back Glenoid review in file.
Likelihood*	Possible
Overall Risk*	Moderate
Any related recall actions?	No.

Proposed ACTION (supplied product)	-HAZARD ALERT
Level of action	Hospital
All end users identifiable?	YES – Direct supply by sponsor
Notification method	Mail
End user action(s)	-Read correspondence
Patient follow up?	-Mandatory
Sponsor action(s)	-confirm receipt of correspondence
Future SUPPLY	-No future supply

Expected CLOSE OUT date	Not expected to take more than 3 months
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Regulator agreement	Agree with the hazard assessment?	<input checked="" type="radio"/> YES / <input type="radio"/> NO
	Agree with proposed action & correspondence?	<input checked="" type="radio"/> YES / <input type="radio"/> NO
	Signed: <i>[Signature]</i>	Date: 6/8/12

were modifications to letter.

Comments

as DW recalls.

Classification system.

Class I – Class I defects are potentially life-threatening or could cause a serious risk to health.

Class II – Class II defects could cause illness or mistreatment, but are not Class I.

Class III – Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

*Overall risk table

	Class III	Class II	Class I
Unlikely	Low	Low	Moderate
Possible	Low	Moderate	High
Likely	Moderate	High	High