

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2015-RN-00240-1
Product Name/Description ⁱⁱⁱ	Catalys Precision Laser System Serial Numbers: 44056912, 44055711, 44072214, 44061512, 44057612 ARTG Number: 194204
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	19/03/2015
Responsible Entity ^{vii}	AMO Australia Pty Ltd
Reason / Issue ^{viii}	<p>Abbott Medical Optics is providing this notification to all customers who use the CATALYS System software version 3.00.05 to make you aware of two issues:</p> <ol style="list-style-type: none"> 1. Loss of suction during treatment A low probability event has been identified where loss of suction during treatment may result in scoring the cornea during lens fragmentation. The CATALYS System has mitigations within its design to prevent this event from occurring. If the system detects a loss of vacuum or forces outside of the acceptable range, the system will stop the laser from activating during treatment and displays a message. 2. Auto-population of cataract incision template A low probability event has been identified for the cataract incision surgeon templates with software version 3.00.05, when selecting and deselecting an eye then selecting the other eye will result in the templates for both eyes having the same parameters. This event only affects the cataract incision surgeon templates.
Recall Action ^{ix}	Recall for Product Correction

Recall Action Instructions^x	<p>AMO is advising that to prevent the incorrect auto-population of cataract incision templates end users must:</p> <p>a) Verify the cataract incisions in the cataract incision a surgeon templates have the correct parameters, correct architecture and are in the desired location prior to saving.</p> <p>b) Within the treatment planning phase and prior to activating the laser, verify all treatment incisions have the correct parameters, correct architecture and are in the desired location which are displayed on the screen.</p> <p>This issue will be corrected in a software update.</p> <p>AMO is also reinforcing the instructions for use with regard to suction loss.</p>
Contact Information^{xi}	1800 266 111 - AMO Australia

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

^{iv} Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

^v Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

^{vi} Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA

^{vii} Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

^{viii} Reason / Issue: Reason for the recall action.

^{ix} Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are three distinct recall actions - recall, recall for product correction and hazard alert.