Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-01205-1
Product Name/Description[iii]	Stellaris PC with Laser System (Cataract extraction/vitrectomy system) Product Code: BL14304 Serial Number : SPC02059 ARTG Number: 127264
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	13/11/2014
Responsible Entity[vii]	Bausch & Lomb Australia Pty Ltd
Reason / Issue[viii]	The Stellaris PC has a software fault, when in surgery, if the surgeon requests a Laser sub-mode change (i.e. from Endo to Endo Continuous) and the system is in "Standby", the system will automatically transition from "Standby" to "Ready" to fire. If the system moves to Ready from Standby, and this has not been specifically commanded by the Surgeon or the Nurse, it raises the possibility that this change may not have been noticed and that the foot pedal could be depressed and the laser may fire unexpectedly.
Recall Action[ix]	Recall for Product Correction
Recall Action Instructions[x]	Bausch and Lomb has developed a software update to address the situation, which will be installed in the affected system. In the meantime, users may continue to use the Stellaris PC laser system. However, they are advised not to request the Laser sub-mode change from Endo to Endo Continuous during surgery until the software update has been implemented.
Contact Information[xi]	02 8918 6216 - Bausch and Lomb Regulatory Affairs

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.