Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2012-RN-00693-3
Product Name/Description[iii]	AcrySof CACHET Phakic Lens (Intraocular lens used for the reduction or elimination of myopia) ARTG Number: 159641
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Action Commencement Date[vi]	11/07/2012
Responsible Entity[vii]	Alcon Laboratories Australia Pty Ltd
Reason / Issue[viii]	This is an update to the previous 'Urgent Recall for Product Correction/Hazard Alert for Surgeons', dated 20th February 2012 (TGA Ref:RC-2012-RN-00145-3) issued by Alcon, and is intended to further inform about an adverse event associated with the Alcon AcrySof CACHET Phakic Lens and additional information gained through the studies allows an update to the Directions for Use (DFU). The updates to DFU are primarily associated with: – Clarification that the Lens is indicated for use for the correction of myopia between -6.0 D and -16.5 D. – Additional information regarding the risk of acute endothelial cell loss (ECL) to strengthen communication of benefits and risks of implantation to the patient – Clarification on the frequency of monitoring for ECL by specular microscopy – Data on patients who experienced a greater than 30% endothelial cell loss (when compared to the preoperative cell count) and/or count below 1500 cells/mm² in the clinical studies
Recall Action[ix]	Hazard Alert
Recall Action Instructions[x]	Customers to be aware of the updated safety information provided in the revised Directions for Use. Physicians are advised to follow the recommended post-operative follow-up schedule as outlined in the Hazard Alert letter.
Contact Information[xi]	02 9452 9200 - Alcon Laboratories

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 /