

Recall detail

Type of Productⁱ	Medical Device
TGA Recall Referenceⁱⁱ	RC-2014-RN-01039-1
Product Name/Descriptionⁱⁱⁱ	Proclear Toric Soft Hydrophilic Contact Lenses Multiple lot numbers manufactured in 2012 ARTG number: 169193
Recall Action Level^{iv}	Retail
Recall Action Classification^v	Class II
Recall Action Commencement Date^{vi}	1/10/2014
Responsible Entity^{vii}	Coopervision Australia Pty Ltd
Reason / Issue^{viii}	Coopervision's investigation of complaints have identified that a limited number of lots were manufactured with the cylinder axis outside the allowable specification. There is not likely to be added medical risk to an incorrect axis lens use, since the patient will notice the blur and visual disturbance right away and report it to the practitioner. Replacement of the lens with the proper power parameter in sphere and cylinder, and/or axis of astigmatism will alleviate the visual blur and disturbance.
Recall Action^{ix}	Recall
Recall Action Instructions^x	Retailers (practitioners) are advised to stop any further patient order fulfilment of the affected lots of Proclear Toric lenses and quarantine them for returning it to Coopervision. Patients will be provided full refund for any affected product returned by them.
Contact Information^{xi}	1800 655 480 - Coopervision Customer Service

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.