

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2013-RN-01254-1
Product Name/Description ⁱⁱⁱ	KAMRA Corneal Inlay (inserted into the natural cornea to treat presbyopia ie, age related hyperopia (far sightedness)). ARTG Number: 182104
Recall Action Level ^{iv}	Hospital
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	13/12/2013
Responsible Entity ^{vii}	Ellex Australia Pty Ltd
Reason / Issue ^{viii}	The manufacturer, AcuFocus is aware of reports of some cases involving use of ophthalmic laser applications in eyes containing KAMRA inlays. During laser treatment, the inlay may absorb the laser and produce heat. This may result in the inlay reducing in size and/or significant thermal damage. In some cases, there were secondary damage to the cornea resulting in scarring. As a result of these case reports, Ellex is providing additional warnings and information relative to the application of various ophthalmic procedures with a KAMRA inlay in situ.
Recall Action ^{ix}	Recall for Product Correction
Recall Action Instructions ^x	The manufacturer has advised the inlays are not defective and function as intended. The purpose of this notification is to provide additional warnings and information with regard to further treatment to patients implanted with the KARMA inlay.
Contact Information ^{xi}	08 8104 5226 - Ellex Regulatory Officer

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.