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CooperVision®

September 17, 2014

URGENT: FIRM INITIATED MEDICAL DEVICE RECALL PROCLEAR TORIC CONTACT LENSES

Dear Eye Care Practitioner:

CooperVision is conducting a voluntary recall of Proclear® toric contact lenses manufactured in 2012. We are taking this action because our routine quality monitoring system has identified that a limited number of lots were manufactured with the cylinder axis outside the allowable specification. Although there is no medical risk, we have decided to conduct this voluntary recall of the affected lots to ensure a positive experience for you and your patients. This recall is being performed with our first-level customers; it is not a consumer-level recall.

Our records indicate you have received some of the affected product. Enclosed is a list of the affected product and lot numbers we have a record of shipping to you. Please take the following actions immediately:

- Examine your inventory for any affected lot numbers
 - Use the enclosed report to inspect your inventory for affected product that is still in your office.
- Stop any further distribution of the specified lots of Proclear toric lenses.
- Quarantine any Proclear toric lenses with the specified lot numbers.
- Within the next five (5) business days, please complete the attached **Recall Response Form** and fax it to 866-484-1048 or scan and email to info@coopervision.com.
 - If you have indicated that you have product to return, you will be contacted by a CooperVision Representative with instructions for pick-up and removal of affected, quarantined product. Your account will be credited once the product is returned and processed.

This action is being taken in full cooperation with the Food and Drug Administration (FDA). The recall only affects Proclear toric lenses with the lot numbers specified on the enclosed list. No other Proclear toric products – or any other CooperVision products – are affected.

We appreciate your assistance and apologize for any inconvenience you may have experienced. If you have any further questions, please feel free to contact your Account Representative or Customer Service at 800-341-2020.

Sincerely,

Christine Moench
Vice President, Global Regulatory Affairs & Quality Assurance