



6101 Bollinger Canyon Rd
Suite 500
San Ramon, CA 94583
www.coopervision.com

URGENT MEDICAL DEVICE CORRECTION

Biofinity XR toric contact lenses

Lot **R24395839**

CooperVision is voluntarily conducting a correction for certain manufacturing lots of Biofinity XR toric contact lenses from the U.S.A. market, effective immediately. CooperVision has determined that you purchased Biofinity XR toric contact lenses affected by this voluntary correction.

Records with your eye care practitioner indicate that you purchased product from the following affected lot(s):

- **R24395839**

The lenses manufactured in the affected lot were made with a misaligned axis resulting in lenses with the incorrect power. Consumers who have received Biofinity XR toric lenses from the affected manufacturing lot(s) may experience poor visual acuity which is resolved by replacing the lens with another having the prescribed parameters. No health or safety risk has been identified with the use of the device.

There have been no adverse events associated with incorrect power Biofinity XR toric contact lenses.

Since the records with your eye care practitioner indicate you have received a product from the affected manufacturing lot(s), we request you take the following actions:

- Please examine any remaining lenses in your possession. The lot number can be found on the back panel of the carton below the expiration date. Below is an example and where to locate the lot number.



- If you have located the affected product, we recommend you return the affected product to your Eye Care Practitioner for credit and/or replacement.

We apologize for any inconvenience. Should you wish to discuss this action, please contact our customer services team at: 800-341-2020, 9:00 AM – 7:00 PM ET, Monday – Friday.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'L Williams'.

Laura Williams
CooperVision, Inc.
Vice President, Global Regulatory Affairs