

URGENT FIELD SAFETY NOTICE

October 31, 2017

Dear Customer:

RE: Voluntary Field Action of specific ACUVUE® ADVANCE®, ACUVUE® OASYS® and 1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lenses (FSCA # QRB-07-2017)

Johnson & Johnson Vision Care Inc., (JJVC) is recalling product lots of ACUVUE® ADVANCE®, ACUVUE® OASYS® and 1-DAY ACUVUE® MOIST® for ASTIGMATISM® Brand Contact Lenses. This Action only affects the lot numbers listed below. No other JJVC lots are affected by this Action.

Brand name	Product Specification	Lot Number
ACUVUE® ADVANCE®	Base Curve 8.7, Refractive Power -4.75D	L002FNL
ACUVUE® ADVANCE®	Base Curve 8.7, Refractive Power -5.00D	L002V94
ACUVUE® ADVANCE®	Base Curve 8.7, Refractive Power -10.00D	B00DHLP
ACUVUE® OASYS®	Base Curve 8.8, Refractive Power -4.50D	L002QH9
ACUVUE® OASYS®	Base Curve 8.8, Refractive Power -4.00D	L002NCS
1-DAY ACUVUE® MOIST® for ASTIGMATISM	Base Curve 8.5 Refractive Power -7.50D, - 1.25 x 180	B00LF41 (Converted Lot Number F00LF41)

The ACUVUE® ADVANCE®, ACUVUE® OASYS® and 1-DAY ACUVUE® MOIST® for ASTIGMATISM® Brand Contact Lens lot numbers are displayed on the individual contact lens package and for product in 6 pack, 30 pack and 90 pack units of measure also on the barcode area on the back of each individual unit carton.

JJVC has voluntarily initiated this Action to assure that you receive the highest quality products. We received a limited number of reports of a brush bristle found between the blister package and foil. The bristles in question were part of a cleaning brush used periodically in our manufacturing process. We have replaced this brush with alternative, safety-tested equipment. No adverse events have been reported as the brush bristle in all instances has been visible to the consumer or customer when opening the contact lens blister package.

The local competent authority has been informed of this Action.

Since you have received potentially affected product, please take the following actions:

- 1. Review your inventory and determine if you have ACUVUE® ADVANCE®, ACUVUE® OASYS® and/or 1-DAY ACUVUE® MOIST® for ASTIGMATISM lenses from the impacted lots.
- 2. STOP using all affected product. You can continue to use all other lots not affected by this voluntary recall.

Johnson & Johnson Vision Care, Inc.

7500 Centurion Parkway Jacksonville, FL 32256

- 3. Please pass this notice on to anyone in your organization who needs to be aware of the issue and ensure that they maintain awareness as necessary.
- 4. **Contact** Customer Service at XXXXXXXX to arrange return and replacement product.
- 5. **Complete** the enclosed Customer Reply Form and return via fax to XXXXXXXX or via email to XXXXXXX@XXX.com, **EVEN IF YOU HAVE NO INVENTORY REMAINING** affected by this recall, JJVC requires this information for reconciliation purposes with regulatory agencies.

As always, any ACUVUE® patient who has a complaint about the product is urged to stop using it and contact Johnson & Johnson Vision Customer Service, the store where the product was purchased, or their eye doctor immediately. If any user experiences persistent irritation, pain or redness, or a change in vision after removing the lens, they should contact their doctor immediately.

Our top priority is patient safety and we hold ourselves to high standards for product quality and customer satisfaction. We remain fully committed to serving our customers with safe and effective products. We recognize the inconvenience this causes you and appreciate your assistance in expediting return of the affected product.

Sincerely,

Roman Lakaschus
Sr. Quality Manager
Johnson & Johnson Vision Care, Inc.
European Vision Center
Hanworth Road
Sunbury-on-Thames
TW16 5LN

FSCA # QRB-07-2017

JJVC FIELD ACTION CUSTOMER REPLY FORM

Please complete and return immediately <u>EVEN IF YOU HAVE NO STOCK</u> via Fax: XXXXXXX or email:

We are returning affected produc	Quantity being Returned
Lot Number	Quantity to be Returned
Customer Name:	
Customer Acct #:	
Address:	
City, State, Postal Code:	
Country	
Telephone Number:	