Johnson Johnson vision

URGENT FIELD SAFETY NOTICE

December 5, 2017

Dear Customer:

RE: Voluntary Field Action of specific 1-DAY ACUVUE[®] MOIST[®] Brand Contact Lenses

Johnson & Johnson Vision Care Inc., (JJVC) is recalling product lots of 1-DAY ACUVUE[®] MOIST[®] 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 Base Curve (BC), Power	30 pack Lot Numbers
DAY ACUVUE [®] MOIST [®]	BC 9.0, -3.75D	2840420107

The 1-DAY ACUVUE[®] MOIST[®] Brand Contact Lens lot numbers are displayed in the barcode area on the back of each individual unit carton as well as on the individual contact lens package.

JJVC has voluntarily initiated this Action to assure that you receive the highest quality products. We received a limited number of reports of lens discoloration and foreign matter in the contact lens blister package. Based on a review by our Medical team, the presence of these small particles is associated with a low potential risk of scratching the cornea, an effect that is typically temporary and reversible. Importantly, no adverse events have been reported. Not all lenses in these lots are affected but all remaining lenses from these affected lots must be returned. We are taking measures to implement even stronger controls in our manufacturing and quality systems.

The local competent authority XXXXXXXXX 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 1-DAY ACUVUE[®] MOIST[®] 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.
- 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. **Use** the enclosed XXXX label to return any affected product related to this action.
- 5. **Contact** Customer Service at XXXXXXXX to arrange replacement product.
- Complete the enclosed Customer Reply Form and return via fax to XXXXXXXX or via email to XXXXXX@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.

Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Jacksonville, FL 32256

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,

Title

Johnson & Johnson Vision Care, Inc.

JJVC FIELD ACTION CUSTOMER REPLY FORM

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

Please place an "X" in one of the boxes below.

All affected products have been used or discarded.

JJVC Sales Representative has returned all affected product inventory on our behalf.

We are returning affected product

Quantity being Returned

Lot Number	Quantity to be Returned
2840420107	

Customer Name:	
Customer Acct #:	
Address:	
City, State, Postal Code:	
Country	
Telephone Number:	

Person completing this form acknowledges the receipt and understanding of the actions, as stated in the Product Recall letter:

Name: (print)

Title/Position

Signature:

Date: