Johnson Johnson vision

URGENT FIELD SAFETY NOTICE

1-DAY ACUVUE[®] MOIST[®] for ASTIGMATISM Brand Contact Lenses

9 September, 2019

Dear Customers,

RE: Voluntary Field Action of Six (6) Lot numbers of 1-DAY ACUVUE® MOIST® for ASTIGMATISM Brand Contact Lenses.

At Johnson & Johnson Vision, our top priority is patient safety and we hold ourselves to high standards for product quality and customer satisfaction. We are voluntarily recalling **six [6]** lots of 1-DAY ACUVUE[®] MOIST[®] for ASTIGMATISM Contact Lenses because they do not meet our quality standards. Importantly, no adverse events have been reported due to this issue. We have identified the cause, taken corrective action, and are planning to implement even stronger manufacturing and quality controls based on learnings from this event. ACUVUE[®] Brand Contact Lenses not impacted by this recall are safe when used as directed and can continue to be used with confidence.

The ACUVUE[®] products affected and distributed in Singapore is limited to **272** boxes. The number of contact lenses associated with this voluntary recall is small. We have not received any adverse incident cases associated with these affected product lots in Singapore. We are liaising closely with Health Sciences Authority, Singapore Optometric Association and Eye Care Professionals as we are committed to continuing to offer high standards of eye health and product quality in Singapore.

S/N	Brand Name	Product Specification Base Curve (BC), Sphere Power, Cylinder Power, Axis	Master Lot	30 pack Lot Numbers
1	1-DAY ACUVUE [®] MOIST [®] for ASTIGMATISM	BC 8.5, -6.00D/-0.75/ 180	395749	3957490101 3957490112
2	1-DAY ACUVUE® MOIST® for ASTIGMATISM	BC 8.5, -6.00D/-1.75/ 180	395750	3957500104 3957500111 3957500112
3	1-DAY ACUVUE® MOIST® for ASTIGMATISM	BC 8.5, -3.50D/-0.75/ 180	395751	3957510102

The ACUVUE[®] product affected is limited to **six [6]** lots:

The 1-DAY ACUVUE[®] MOIST[®] for ASTIGMATISM Brand Contact Lens lot numbers are displayed in the barcode area on the back or side of each individual unit carton. The lot number is also present on the foil of each individual blister package of the contact lens.

Example for Illustrative Purposes Only:

• **Outer Box:** Under the first barcode on left of the back face, the lot number is the first 7 numbers and/or letters written next to "LOT."



• **Blister Package**: Please check the first 7 digits of the numbers written at the bottom next to "LOT" on the foil.



Since you have received potentially affected product, please **take the following actions, EVEN IF YOU HAVE NO INVENTORY REMAINING** affected by this recall. Johnson & Johnson Vision requires this information for reconciliation purposes with regulatory agencies.

- 1. Review your inventory and determine if you have **1-DAY ACUVUE® MOIST® for ASTIGMATISM** lenses from the impacted lots in the above table.
- 2. Set aside and **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. **Complete** the enclosed Customer Reply Form **EVEN IF YOU HAVE NO INVENTORY REMAINING** affected by this recall. Send an electronic soft copy of the completed form to your J&J representative.

5. Place the original hard copy with affected product to be returned. JJVC requires this documentation for reconciliation purposes with regulatory agencies. If you have no product to be returned, your J&J representative will arrange for collection of the hard copy.

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 Optometrist immediately. If any user experiences persistent irritation, pain or redness, or a change in vision after removing the lens, they should contact their optometrist or doctor immediately.

ACUVUE® Support: 800-101-3130 | support@acuvue.com.sg

Operating Hours: Monday to Friday, 8am to 4pm

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, sincerely apologize, and appreciate your assistance in expediting return of the affected product.

Sincerely,



Patricia Yeo, Business Unit Head, Singapore

Johnson & Johnson Vision Care, Pte Ltd

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FIELD ACTION CUSTOMER REPLY FORM

Please complete within 24 hours, <u>EVEN IF YOU HAVE NO STOCK</u>. Once complete, please send an electronic copy to your sales representative. A courier company will collect the hard copy over the next few days.

Please place an "X" in the relevant boxes below. (You may use more than 1 box)

I was notified of the product recall and affected lot numbers by JJVC Sales Representative.

All affected products have been used or discarded.

JJVC has collected all affected product inventory.

Lot Number	Quantity to be Returned
<mark>3957490101 (30 pack)</mark>	
<mark>3957490112 (30 pack)</mark>	
<mark>3957500104 (30 pack)</mark>	
<mark>3957500111 (30 pack)</mark>	
<mark>3957500112 (30 pack)</mark>	
<mark>3957510102 (30 pack)</mark>	

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: