Johnson & Johnson Vision
European Vision Centre
Sunbury-on-Thames
TW16 5LN

Customer Details

URGENT FIELD SAFETY NOTICE

1-DAY ACUVUE® MOIST for ASTIGMATISM Brand Contact Lenses

September xx, 2019

RE: Voluntary Product Removal/Recall of Two Full and One Partial Master Lot of 1-DAY ACUVUE® MOIST for ASTIGMATISM Brand Contact Lenses (Master Lot Numbers 395749, 395750, and 395751)

Dear Customer:

Johnson & Johnson Vision Care, Inc ("Johnson & Johnson Vision") is recalling certain product lot(s) of 1-DAY ACUVUE® MOIST for ASTIGMATISM Brand Contact Lenses. **This action only affects the lot numbers indicated below. No other lots are affected by this action.**

Brand name	Product Specification Base Curve (BC), Power	Master Lot Number	30-Pack Lot Numbers
1-DAY ACUVUE® MOIST for ASTIGMATISM	BC 8.5, -6.00D/-0.75 X 180	395749	3957490101 3957490102 3957490103 3957490104 3957490105 3957490106 3957490107 3957490108 3957490109 3957490110 3957490111 3957490112
1-DAY ACUVUE® MOIST for ASTIGMATISM	BC 8.5, -6.00D/-1.75 X 180	395750	3957500101 3957500102 3957500103 3957500104 3957500105 3957500106 3957500107 3957500108 3957500109 3957500110 3957500111 3957500112
1-DAY ACUVUE® MOIST for ASTIGMATISM	BC 8.5, -3.50D/-0.75 X 180	395751	3957510101 3957510102 3957510103 3957510104 3957510105

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.

Johnson & Johnson Vision has voluntarily initiated this action to ensure you receive the highest quality products. We received a limited number of reports of foreign matter on the contact lens or in the contact lens blister solution. While there has been one report of lens use that resulted in discomfort and eye redness, importantly, there have been no reports of serious adverse events.

Based on a safety review by our Medical team, the presence of these small particles is associated with low potential risk if a patient inserts an affected lens in their eye. If the particles weren't noticed before insertion in the eye, it could result in eye redness, discomfort, or corneal abrasion.

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.

The relevant Competent Authorities "Health Products Regulatory Authority " and Notified Body have been informed of this Action. 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: **Master Lot 395749** (3957490101, 3957490102, 3957490103, 3957490107, 3957490108, 3957490109, and 3957490112)**, Master Lot 395750** (3957500108, 3957500109, and 3957500112), and **Master Lot 395751** (3957510102, and 3957510103).
2. **STOP** using all **affected** product. You can continue to use all other lots not affected by this voluntary recall.
3. Please contact your patients that may have received any of the affected product and instruct them to discontinue use immediately and return product to you for replacement.
4. Please pass this notice on to anyone in your organization who needs to be aware of the issue and ensure they maintain awareness as necessary.
5. **Contact** Customer Service at 1800 812 100 to arrange replacement product free of charge or a Credit.
6. **Complete** the enclosed Customer Reply Form and return via email to UKCS@visgb.JNJ.com , Customer Service will then arrange collection for the products being returned.

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

Sincerely,

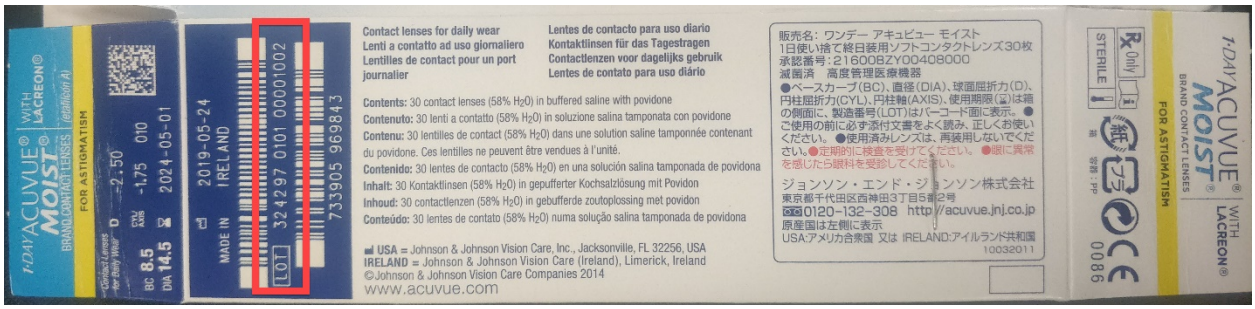
Jakob Sveen
General Manager UK & Ireland
Johnson & Johnson Vision

Lot Number Location

The lot number is displayed in the barcode area on the back or side of each individual unit carton (below for example). 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 written next to “LOT.”



- **Blister Package:** Please check the numbers written at the bottom next to “LOT” on the foil.

Johnson & Johnson Vision

FIELD ACTION CUSTOMER REPLY FORM

Please complete and return immediately EVEN IF YOU HAVE NO STOCK via email: UKCS@visgb.JNJ.com

Please place an "X" in the box below to indicate all required customer contacts completed

☐ All required customer contacts completed.

Please place an "X" in one of the boxes below to indicate action taken.

☐ All affected products have been used or discarded.

☐ J&J Vision 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
3957490101 (30 pack)	
3957490102 (30 pack)	
3957490103 (30 pack)	
3957490107 (30 pack)	
3957490108 (30 pack)	
3957490109 (30 pack)	
3957490112 (30 pack)	

Lot Number	Quantity to be Returned
3957500108 (30 pack)	
3957500109 (30 pack)	
3957500112 (30 pack)	

Lot Number	Quantity to be Returned
3957510102 (30 pack)	
3957510103 (30 pack)	

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: _____