

Johnson & Johnson Vision Care, Inc.

7500 Centurion Parkway

Jacksonville, FL 32256



## URGENT FIELD SAFETY NOTICE

### 1-DAY ACUVUE® TruEye® Brand Contact Lenses

December 26, 2019

**RE: Voluntary Product Removal/Recall of one lot of 1-DAY ACUVUE® TruEye® brand contact lenses** (30-Pack Lot Number 5840330112, which may also be packaged into 90-Pack Lot Number 5840335107)

Dear Customer:

Johnson & Johnson Vision Care, Inc. ("Johnson & Johnson Vision") is recalling one product lot(s) of 1-DAY ACUVUE® TruEye® 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	30-Pack Lot Numbers	90-Pack Lot Numbers
1-DAY ACUVUE® TruEye®	BC 8.5, -5.00D, 14.2 Diameter	5840330112	5840335107

The 1-DAY ACUVUE® TruEye® 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 confirmed reports of a lens being 'off power' which the consumer may recognize as not accurately correcting the vision (some distortion or blurriness). Upon investigation, it was determined that a lot mix occurred that resulted in a mixed lot of mislabeled (lens power) lenses. Not all lenses in these lots are affected and there is no significant health risk requiring medical intervention related 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.

The relevant Competent Authorities 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® TruEye®** lenses from the impacted lots:
  - a. **30 Lens Pack Lot 5840330112** and **90 Lens Pack Lot 5840335107**. Please note, if you see the lot number 5840335107 on your 90-pk, you will need to open that 90-pk and look for lot number 5840330112 on the individual 30-pks.
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 who 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 to anyone in your organization who needs to be aware of the issue and ensure they maintain awareness as necessary.
5. **Use** the enclosed **XXXX** label to return any affected product related to this action.
6. **Contact Customer Service at XXXXXXXX** to arrange replacement product.
7. **Complete** the enclosed Customer Reply Form and return via fax to **XXXXXXXXX** via email to [vpweb@visus.jnj.com](mailto:vpweb@visus.jnj.com).

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.

At Johnson & Johnson Vision, we hold ourselves to high standards for product quality and customer satisfaction. We remain fully committed to serving our customers with quality, effective products. We apologize for the inconvenience this causes you and appreciate your assistance in expediting return of the affected product.

Sincerely,

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Alvin LOH  
Business Regional Quality Manager, ASEAN  
Johnson & Johnson Vision

Johnson & Johnson Vision  
FIELD ACTION CUSTOMER REPLY FORM

Please complete and return immediately EVEN IF YOU HAVE NO STOCK via Fax: 904-443-3442 or email: [vpiweb@visus.jnj.com](mailto:vpiweb@visus.jnj.com)

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

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

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
5840330112	

<b>Customer Name:</b>	
<b>Customer Acct #:</b>	
<b>Address:</b>	
<b>City, State, Postal Code:</b>	
<b>Country</b>	
<b>Telephone Number:</b>	

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:** \_\_\_\_\_