

Johnson & Johnson Vision
European Vision Centre
8 Hanworth Road
Sunbury-on-Thames, TW16 5LN

URGENT
MEDICAL DEVICE FIELD SAFETY NOTICE

May xx, 2021

Dear Johnson & Johnson Vision Customer:

RE: Voluntary Recall of ACUVUE® Vita® Brand Diagnostic Lenses

Brand name	Product Specification	Lot Number on box	Lot Number on individual contact lens package
ACUVUE® Vita®	Base Curve 8.8 Refractive Power -1.50	B00WWWL	B00WWWL

Johnson & Johnson Vision Care, Inc. (JJVC, part of the Johnson & Johnson Vision group of companies) is voluntarily recalling one lot of **ACUVUE® Vita® Brand Diagnostic Lenses**. **This action only affects this one lot number B00WWWL. No other JJVC lots are affected by this Action.** The ACUVUE® Vita® Brand Contact Lens lot number is displayed in the barcode area on the back of each individual unit carton as well as on the individual contact lens package.

This field action is being initiated to voluntarily recall one lot of ACUVUE® Vita® Brand Diagnostic lenses due to the potential for a limited number of individual contact lens packages to have an incomplete packaging seal. The integrity of primary packaging (blister packs) may be compromised for this diagnostic lot of product. This compromise can potentially cause leakage of lens packing solution. There is also a risk that the contact lens and packing solution may become unsterile. Lenses from non-sterile packaging may pose a risk for infection if the lens is inserted into the eye. The chances of this occurring are remote. Importantly, no complaints or adverse events have been reported due to this issue. Johnson & Johnson Vision Care Inc. (JJVC) has taken corrective measures to help ensure this issue does not recur. ACUVUE® Brand Contact Lenses not affected by this recall are safe when used as directed and can continue to be used with confidence.

You are receiving this notice because our records indicate that you received ACUVUE® Vita® Brand Diagnostic Lenses lot number B00WWWL impacted by this Action.

The National Competent Authority Health Products Regulatory Authority and Notified Body have been informed of this Action..

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

1. **Review** your inventory and determine if you have **ACUVUE® Vita® Brand Diagnostic lenses from the impacted lot: B00WWWL**
2. **STOP** using and remove from your inventory all **affected** product. Note: 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. Please contact your patients that may have received any of the affected product and ask them to discontinue use and return to you for replacement.
5. Customer Service, at xxxxxxxx will arrange for you the return and replacement of any affected product.
6. **Complete** the enclosed Customer Reply Form and return via email to xxxxxx.jnj.com, **EVEN IF YOU HAVE NO INVENTORY REMAINING** affected by this recall. JJVC requires this information for reconciliation purposes with regulatory agencies. The completed Customer Reply Form should be faxed or emailed within **3 business days of receipt of this letter**.

As always, any ACUVUE® patient who has a complaint about the product is urged to stop using it and contact Johnson & Johnson Vision Care Customer Service, at xxxxxx, 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's top priority is patient safety and holds to high standards for product quality, customer satisfaction, and remains fully committed to serving customers with safe and effective products.

This voluntary action reflects JJVC's commitment to high quality standards and ensuring that our products fully meet your expectations. We recognize the inconvenience this causes you and appreciate your assistance in expediting the return of this product.

Sincerely,

[Signature and Title]

Johnson & Johnson Vision Care, Inc.



JJVC Product Recall Letter Dated [May/xx/2021]

ACUVUE® Vita® Brand Diagnostic Lens RECALL 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 one of the boxes below.

☐
☐

We have no stock of lenses involved in the recall.

We are returning affected products. Comment: _____

Lot Numbers	Quantity of lenses to be Returned
B00WWWL	

Customer Name:	
Customer Account #	
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: _____