Rev 2: February 2020
FSN Ref: FSN2025-01 FSCA Ref: FA-0000102

Date: 10 Jun 2025

Field Safety Notice
ACUVUE® OASYS MAX 1-Day MULTIFOCAL

For Attention of:name of the Customer

Contact details of local representative (name, e-mail, telephone, address etc.)
Local country contact details

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Field Safety Notice (FSN)
ACUVUE® OASYS MAX 1-Day MULTIFOCAL
URGENT: MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

1. Information on Affected Devices	
1.	1. Device Type(s)
	Soft corrective contact lens, daily-disposable, sterile.
1.	2. Commercial name(s)
	ACUVUE® OASYS MAX 1-Day MULTIFOCAL
1.	3. Unique Device Identifier(s) (UDI-DI)
	0733905a00011BK
1.	4. Primary clinical purpose of device(s)
	Vision correction
1.	5. Device Model/Catalogue/part number(s)
	888290919116
1.	6. Affected lot number range
	J003Q72 1D MAX MULTIFOCAL 8.4 -2.00 LOW 30P RX

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	We are voluntarily initiating a recall of the above referenced lots of ACUVUE® OASYS MAX 1-Day MULTIFOCAL contact lenses due to a defect that may lead to unexpected visual disturbances when worn. No other ACUVUE® Brand of Contact Lenses are included in this voluntary recall.
2.	2. Hazard giving rise to the FSCA
	Following our rigorous quality inspections, we identified a high density of microbubbles (microscopic voids within the contact lens) observed in specific lots during our quality control checks. These microbubbles won't cause medical harm to your patients but may be associated with visual disturbances such as glare, halo, starburst, and decreased contrast, particularly in low-light conditions. If patients experience these related visual issues, they will resolve after the removal of the lens.
2.	3. Probability of problem arising
	We have not received any complaints, nor have any adverse events been reported at this time due to this issue.
2.	5. Other information relevant to FSCA
	You are receiving this notice because our records indicate that you have received contact lenses impacted by this recall. Below we have shared detailed instructions for what to do with the impacted contact lenses you may have on hand. We regret any inconvenience this may cause and are here to support you by replacing the affected lenses – please contact your local Customer Service Team at <Insert Local Info here> for further information, and to address any questions or concerns about ACUVUE® Brand Contact Lenses.

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3. Type of Action to mitigate the risk

3. **1. Action To Be Taken by the User**

☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device

☐ On-site device modification / inspection

☐ Follow patient management recommendations

☐ Take note of amendment / reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

1. **Review** if any of your inventory contains contact lenses impacted from the lot numbers listed below

Brand Name	Product Specification	SKU	Lot Number
ACUVUE® OASYS MAX 1-Day MULTIFOCAL	1D MAX MULTIFOCAL 8.4 -2.00 LOW 30P RX	888290919116	J003Q72

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. Customer Services will arrange for you the return and replacement of any affected product.
5. **Complete** the enclosed Customer Reply Form and return via email to Customer Services <Insert Local Info here> for **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 emailed or faxed within **3 business days of receipt of this letter**.

3.	2. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes

3. **3. Action Being Taken by the Manufacturer**

☒ Product Removal
☐ Software upgrade
☐ Other
☐ On-site device modification/inspection
☐ IFU or labelling change
☐ None

Swift measures have been put in place to ensure the issue does not recur so you and your patients can feel confident you'll continue to receive the high-quality contact lenses you know and trust from ACUVUE®.

4. General Information		
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	4. List of attachments/appendices:	ACUVUE® OASYS MAX 1-Day MULTIFOCAL Lens FSCA CUSTOMER REPLY FORM
4.	5. Name/Signature	Miranda Angelovski EMEA Commercial Quality Manager

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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ACUVUE® OASYS MAX 1-Day MULTIFOCAL Lens FSCA CUSTOMER REPLY FORM

Please complete and return immediately EVEN IF YOU HAVE NO STOCK via email: <Insert Local Info here>

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

Company Name:	
Address:	
City, State, Zip 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: _____