Alcon Eye Care UK Limited
Park View, Riverside Way
Watchmoor Park, Camberley
Surrey, GU15 3YL

URGENT: MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION	
Description	**Potential Incomplete Seal for Specific lots of Alcon Standalone Vitrectomy Consumables**
Product Reference	**Alcon Standalone Vitrectomy Consumables**
Market Action Identifier	**2025.011**

XX August 2025

«Account_Name»
«Account_Address»
«City», «State» «Zip_Code»
Account# «Account #»

Dear «Account_Name»,

The purpose of this letter is to notify you that Alcon has initiated a Medical Device Field Safety Corrective Action for specific lots of Alcon Standalone Vitrectomy Consumables.

The following potentially affected product has been shipped to your facility:

Product #	Product Description	Affected Lot(s)
<Product #>	<Product description>	<affected lot(s)>

Description of the Issue

Alcon is conducting this Medical Device Field Safety Corrective Action of Alcon Standalone Vitrectomy Consumables as there is potential for some pouches within impacted lots to have an incomplete seal. Please see photos next page for examples of incomplete seal.

Due to the risk that the sterile barrier may be compromised, Alcon is initiating a Field Safety Corrective Action for potentially affected lots. The use of non-sterile surgical products may increase the risk of post-operative infection, which may require additional medical and/or surgical intervention.

This event was identified internally, and to date Alcon has not received any reports of customer complaints or adverse events related to this issue.

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Exhibit 1: Images of Incomplete Seal

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Actions to be taken by the Customer / User

We are asking that you locate and dispose of any affected lots of Alcon Standalone Vitrectomy Consumables remaining in your inventory. To comply with this Medical Device Field Safety Corrective Action and request the replacement of any unused product, please take the following steps:

1. Review your inventory to determine if you have any unused affected product within your facility. **See table on page 1 for affected Standalone Vitrectomy Consumable lots** shipped to your location.
2. Segregate and **dispose** of any unused affected product from your inventory, irrespective of if it matches the image (on page 2) or not.
3. Respond to Alcon indicating your understanding of these instructions **even if you have zero (0) units remaining in inventory** by completing and returning the attached "Response Form" and returning to Alcon via email to gb.quality@alcon.com
4. Upon receipt of acknowledgement, Alcon will provide a replacement of the affected product as required.
5. Please forward this notification to all departments within your organization who may be in possession of this affected product; and any other organization to which this product may have been transferred.

Contact for Further Questions about this Medical Device Field Safety Corrective Action

Alcon has reported this issue to Health Authorities in accordance with applicable regulations.

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon via web (https://notifeye.alcon.com) or by email (qa.complaints@Alcon.com)

Adverse events or quality problems experienced with the use of this product may also be reported to the Health Authorities online at:

UK

Medicines & Healthcare products Regulatory Agency (MHRA) https://yellowcard.mhra.gov.uk/

Ireland

Health Products Regulatory Authority (HPRA)

https://www.hpra.ie/homepage/about-us/report-an-issue/mdiur

Should you have any questions or concerns about this matter please contact your Alcon Sales Representative or contact Alcon Customer Service:

UK & Ireland

Email: uk.customerservicehelpdesk@alcon.com

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Sincerely,

James Comper
Regulatory Affairs Director UK/Ireland
gb.reg@alcon.com
Tel: +44 7880 002 712

Alcon

RESPONSE FORM	
Potential Incomplete Seal for Specific lots of Alcon Standalone Vitrectomy Consumables MA# 2025.011	«Account_Name» «Account_Address» «City», «State» «Zip_Code» Account# «Account #»

To comply with this Medical Device Field Safety Corrective Action, please take the following steps:

1. Review your inventory to determine if you have any unused affected product within your facility. **See table on page 1 for affected Standalone Vitrectomy Consumable lots** shipped to your location.

Product #	Product Description	Affected Lot(s)	Units Disposed

2. Segregate and **dispose** of any unused affected product from your inventory, irrespective of if it matches the image (on page 2) or not.
3. Respond to Alcon indicating your understanding of these instructions **even if you have zero (0) units remaining in inventory** by completing and returning the attached "Response Form" and returning to Alcon via email to gb.quality@alcon.com.
4. Upon receipt of acknowledgement, Alcon will provide a replacement of the affected product as required.
5. Please forward this notification to all departments within your organization who may be in possession of this affected product; and any other organization to which this product may have been transferred.

Please return this Response Form via email to Alcon:
Email: gb.quality@alcon.com

Your signature below attests that you have read and understood this notification.

Signature:	**Date:**
Printed Name:	
Title:	