



<b>URGENT: MEDICAL DEVICE FIELD SAFETY NOTIFICATION</b>	
<b>Description</b>	<b>Potential Incomplete Seal for Specific lots of Alcon Standalone Vitrectomy Consumables</b>
<b>Product Reference</b>	<b>Alcon Standalone Vitrectomy Consumables</b>
<b>Market Action Identifier</b>	<b>2025.011</b>

August 08, 2025

Vista Vision SRL  
Str Pavlosin nr 13, Timisoara, Timis  
Romania  
n.hirsova@vistavision.ro

Dear Ms. Nicoleta Hirsova,

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

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

<b>Product #</b>	<b>Product Description</b>	<b>Affected Lot(s)</b>
8065751577	CHANDELIER,25GA,W/RFID	17C2RY

#### **Description of the Issue**

Alcon is conducting this Medical Device Field Safety Notification 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 recalling 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.

**Exhibit 1: Images of Incomplete Seal**



## 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 Notification 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 **return to Alcon Romania** of any unused affected product from your inventory.
3. Call Alcon Customer Service to arrange for replacement of your affected inventory of Alcon Standalone Vitrectomy Consumables.
4. 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 or fax.
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 Notification

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon at [qa.complaints@alcon.com](mailto:qa.complaints@alcon.com) or by phone.

Should you have any questions or concerns about this matter, please feel free to call Alcon Customer Service at [customerservice.romania@alcon.com](mailto:customerservice.romania@alcon.com) or contact your Alcon Sales Representative.

Sincerely,

**Marius Popescu**

QA/RA Manager Romania & Moldova

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Bucharest, 020334 Romania

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[marius.popescu@alcon.com](mailto:marius.popescu@alcon.com)

Digitally signed by Popescu, Marius  
DN: cn=Popescu, Marius, ou=PDF  
Internal Signing, o=Alcon Vision, LLC  
Date: 2025.08.08 18:24:33 +03'00'

RESPONSE FORM			
<b>Potential Incomplete Seal for Specific lots of Alcon Standalone Vitrectomy Consumables</b> <b>MA# 2025.011</b>		Vista Vision SRL Str Pavlosin nr 13, Timisoara, Timis Romania n.hirsova@vistavision.ro	
<p>To comply with this Medical Device Field Safety Notification, please take the following steps:</p> <ol style="list-style-type: none"> <li>1. Review your inventory to determine if you have any unused affected product within your facility. See table below for affected Standalone Vitrectomy Consumable lots shipped to your location.</li> </ol>			
<b>Product #</b>	<b>Product Description</b>	<b>Affected Lot(s)</b>	<b>Units Returned</b>
8065751577	CHANDELIER,25GA,W/RFID	17C2RY	<div style="background-color: yellow; width: 20px; height: 10px;"></div>
<ol style="list-style-type: none"> <li>2. Segregate and <b>return to Alcon Romania</b> of any unused affected product from your inventory.</li> <li>3. Call Alcon Customer Service to arrange for replacement of your affected inventory of Alcon Standalone Vitrectomy Consumables.</li> <li>4. Respond to Alcon indicating your understanding of these instructions <b>even if you have zero (0) units remaining in inventory</b> by completing and returning this "Response Form" and returning to Alcon via email.</li> <li>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.</li> </ol>			
<p align="center"><b>Please return this Response Form via email to Alcon:</b>  E-mail : <a href="mailto:marius.popescu@alcon.com">marius.popescu@alcon.com</a></p>			
<p align="center"><b><i>Your signature below attests that you have read and understood this notification.</i></b></p>			
<b>Signature:</b>		<b>Date:</b>	
<b>Printed Name:</b>			
<b>Title:</b>			