

<b>URGENT: VOLUNTARY MEDICAL DEVICE REMOVAL</b>	
<b>Description</b>	<b>Alcon AutonoMe™ Pre-loaded Delivery System</b>
<b>Product Reference</b>	<b>CNA0T0.240</b>
<b>Lot Reference</b>	<b>25238775</b>
<b>Market Action Identifier</b>	<b>2022.010</b>

May XX, 2022

«Account\_Name»

«Account\_Address»

«City», «State» «Zip\_Code»

«Contact\_Name»

Dear Healthcare Professional,

We would like to inform you that Alcon has initiated a Voluntary Medical Device Removal for one specific lot (25238775) of the Clareon® IOL with AutonoMe® Delivery System (CNA0T0.240). Based on our investigation, there is the potential for a limited number of 17.5D lenses to be included within this one lot of the 24.0D Clareon® IOL with AutonoMe® Delivery System.

Alcon has identified that units from this affected lot may currently be within the inventory of your facility.

Affected product and lot:

<b>Product</b>	<b>Reference/SKU Number</b>	<b>Lot Number</b>
Clareon® IOL with AutonoMe® Delivery System	CNA0T0.240	25238775

If an incorrect IOL with a 6.5D difference were to be implanted in a patient, a significant post-operative refractive error would be expected. Patients with a significant postoperative refractive error are expected to experience symptoms that include reduced uncorrected vision, which may require additional intervention such as spectacle correction or surgical intervention. In the event that an IOL(s) from this lot has/have been implanted, we recommend that you confirm the residual refractive error as part of your normal postoperative care.

## Actions to be taken by the Customer / User:

Our records indicate that you have received one or more units of this specific lot of the 24.0D Clareon® IOL with AutonoMe® Delivery System. We are asking that you locate and return the Alcon 24.0D Clareon® IOL with AutonoMe® Delivery System with lot 25238775 in accordance with the attached instructions.

To assist in this Voluntary Medical Device Removal and the required return of any unused product, please take the following steps:

1. Review your consignment to determine if you have any unused product of lot 25238775 of the Clareon® IOL with AutonoMe® Delivery System (CNA0T0.240) within your facility.  
*Note: The first eight (8) digits of the SN on the carton label are the lot number. See numbers outlined in red in the image below:*



2. Separate any unused product of lot 25238775 of the Clareon® IOL with AutonoMe® Delivery System from your inventory.
3. An Alcon associate will reach out to you directly to arrange for the return and replacement of your affected inventory of lot 25238775 of the Clareon® IOL with AutonoMe® Delivery System.
4. Fill out the attached 'Response Form', even if you have zero (0) units remaining in inventory and return the form to Alcon using the contact information provided on the form.
5. Please forward this information to:
  - all departments within your organization who may be in possession of this specific lot (25238775) of the Clareon® IOL with AutonoMe® Delivery System (CNA0T0.240); and
  - any other organization to which this lot may have been transferred.

**Contact for Further Questions about this Voluntary Market Removal Notice:**

In the event you have experienced adverse events or product quality issues related to this communication, please contact Alcon via email (<<<insert local complaint email contact>>) or by phone (<<insert local phone contact information>>).

This event has been reported to <<insert local competent authority>>. If there have been adverse events or quality problems experienced with the use of this product, they may also be reported to the <<insert local Competent Authority contact information if available>>.

Should you have any questions or concerns about this matter, please feel free to call Customer Service at <<insert local phone contact information>> or contact your Alcon Sales Representative.

<<Insert Local Contact info>>

## RESPONSE FORM

**Clareon® IOL with AutonoMe® Delivery System  
MA# 2022.010**

«Account\_Name»  
«Account\_Address»  
«City», «State» «Zip\_Code»  
«Contact\_Name»  
«Telephone\_Number»  
«Account #»

**Affected Product:**

Product	Lot Number	Quantity to be Returned
Clareon® IOL with AutonoMe® Delivery System	25238775	

**Please follow these important steps:**

1. Review your consignment inventory to determine if you have any unused product of lot 25238775 of the Clareon® IOL with AutonoMe® Delivery System.
2. Segregate any unused product of lot 25238775 of the Clareon® IOL with AutonoMe® Delivery System.
3. An Alcon associate will reach out to you directly to arrange for the return and replacement of your affected inventory of lot 25238775 of the Clareon® IOL with AutonoMe® Delivery System.
4. Fill out this Response Form, even if you have zero (0) units in inventory.
5. Return this Response Form via fax or email to Alcon, using the following contact information:

**<<INSERT LOCAL ALCON CONTACT INFO HERE>>**

*Your signature below attests that you have read and understood the information in this notice.*

**Signature:**

**Printed Name:**

**Title:**

**Date:**