URGENT: FIELD SAFETY NOTICE
REVISED QTY

Commercial Name of Affected Product:	**Alcon® Small Volume Syringes 200µL Luer-Lok™ 8065102740**
Reference(s):	**Lot P1642918H / Lot P1561004H**
FSCA Identifier:	**2015.009**
Type of Action:	**Medical Device Recall**

February 10, 2015

Dear Valued Alcon Customer,

Alcon is conducting a medical device recall of its Alcon® Small Volume Syringes 200µL Luer-Lok™ syringes due to the possible presence of fiber material between the stopper and the barrel. Alcon has received information regarding potential issues associated with Alcon® Small Volume Syringes 200µL Luer-Lok™ (Lot number P1642918H).

Based on our internal investigation indicates Alcon cannot eliminate the possibility of foreign material (fibers) in syringe lot P1561004H in addition to lot P1642918H. The presence of fiber material between the stopper and the barrel may pose a potential hazard should the fiber become dislodged. To date no harms or any associated adverse events have been reported in regards to this issue. However, Alcon has chosen to initiate this voluntary recall of the possible impacted lots.

According to our records, you have been provided syringes from the following Alcon lot numbers:

Syringe Number	Lot ID	QTY
8065102740	P1561004H	1,700
	P1642918H	5,500

National Competent Authority will be notified of this action.

Details on Affected Device:

The Alcon® Small Volume Syringes 200µL Luer-Lok™ syringe is a single use, disposable, sterile piston syringe. The syringe consists of three components: a barrel, a plunger, and a stopper. The syringe is intended to inject fluids into the body, ports, and I.V. lines.

Description of the Problem:

Based on our internal investigation Alcon cannot eliminate the possibility of foreign material (fibers) in syringe lot P1561004H in addition to Lot P1642918H. The presence of fiber material between the stopper and the barrel may pose a potential hazard should the fiber become dislodged. To date no harms or any associated adverse events have been reported in regards to this issue. However, Alcon has chosen to initiate this voluntary recall of the possible impacted lots.

Actions to be taken by the Customer/ User:

To assist us in this voluntary recall, please take the following steps:

1. **Immediately stop further use of the affected Alcon® Small Volume Syringes-200µL Luer-Lok™**
2. Review your inventory to determine if you have any affected units
3. Segregate the potentially-affected product to ensure it is not used
4. Return the attached Response Form via fax or email to Alcon
5. **Please fill out and return the attached "Response Form" even if you have zero (0) units in inventory**

Please Note: Please return any unused syringes such that Alcon may issue you credit for these products. If you have any further questions or need assistance with credit for you product, please contact the ***Alcon Houston Controller at 1-713-295-4310***.

Transmission of this Notice:

Please immediately forward this information to all departments within your organization who may be using or ordering the Alcon® Small Volume Syringes 200µL Luer-Lok™ syringes. Additionally, please ensure that a copy of this notification is provided to any other organizations to which the affected device lots have been transferred.

Contact reference person:

We appreciate your cooperation and sincerely regret any inconvenience that this may cause you. We hope this action reassures you of our commitment to provide you with the highest quality vision care products and continued quality excellence for you and your patients.

Should you have any questions or concerns about this matter, please contact Alcon at:

Alcon Laboratories (UK) Ltd.
Frimley Business Park
Frimley, Camberley
GU16 7SR, Surrey, United Kingdom
authorised.representative@alcon.com

Sincerely,

[redacted]

For the Authorised Representative
Alcon Laboratories (UK) Ltd.
+44 1276 673 390
+32 3890 2840

Response Form

Please follow these important steps:

1. **Immediately stop further use of the affected Alcon® Small Volume Syringes 200µL Luer-Lok™**
2. Review your inventory to determine if you have any affected units
3. Segregate the potentially-affected product to ensure it is not used
4. Return the attached Response Form via fax or email to Alcon
5. **Please fill out and return the attached "Response Form" even if you have zero (0) units in inventory**

Email: Market.Actions@Alcon.com or authorised.representative@alcon.com

Please return the Response Form even if you do not have any inventory from these lots. Your signature bellow attests that you have read and understood Alcon's request and instructions.

Please contact Alcon Customer Service at 800-862-5266 to arrange for the return of your inventory.

Catalog Order #	Lot ID	# Units in Inventory

Signature of Facility Representative:

Printed Name and Title:

Date: