

**URGENT - MEDICAL DEVICE RECALL**

May 29, 2015

«Customer Name»  
«Account #»  
«AddressBlock  
»

Dear Valued Customer:

This letter is to notify you of Bausch + Lomb's voluntary recall of the referenced serial numbers below of the SofPort & SoFlex intraocular lenses. Based on a limited number of complaints received for broken haptics during lens loading and insertion, an investigation was initiated. This investigation resulted in Bausch & Lomb determining that a portion of a lot of haptic material is performing differently than other lots in terms of material elongation properties. This lot of haptics was used to produce a quantity of IOLs in 2014. We ask that you immediately remove these lenses from your inventory and hold them for return to Bausch + Lomb.

**PRODUCT DETAILS****Name:** SofPort & SoFlex**Models:** LI61AO & LI61SE

Refer to attached list of serial numbers impacted that you received

**No other Bausch + Lomb IOLs are affected by this action.**

If you have already implanted the identified IOLs, there is no indication that the implanted IOLs present a health issue or performance concern. Therefore, patients should be followed as per your usual standard of care. All reports of broken haptics have occurred during lens loading or insertion. This could result in the need to exchange the lens during the original surgery.

Your B&L representative will be contacting you to execute the below process. Your representative and you will work together to execute the following:

- Segregate the identified IOLs
- Return the IOLs through your B&L representative or by using the prepaid shipping label included in this package.
- Order replacement product through customer service (800) 338-2020 or your B&L representative. If replacement product is needed for a scheduled surgery before your full return can be processed, please contact your B&L representative to expedite shipment of the IOL.
- The customer will need to complete & return the acknowledgement form included in this package.

Please be assured that we take the safety and quality of our products very seriously. Our customers are our top priority and we want to ensure they have a high-quality product which meets their daily needs.

Your prompt attention to this important matter and return of all unused product from these lots is greatly appreciated. Please contact Bausch + Lomb at (800) 338-2020 if you have any questions.

John Boselli  
VP of Quality, Medical Devices  
Bausch + Lomb

## SofPort & SoFlex IOL Recall Acknowledgement Form

«Customer Name»  
 «Account #»  
 «AddressBlock  
 »

This is to acknowledge receipt of the above referenced recall notification dated May 29, 2015.

The following serial numbers are on record as already being implanted by your facility:

Serial Number	Model/Diopter

The following serial numbers may still be located in your facility. Please review your inventory, quarantine the product, and provide Bausch + Lomb with the following information regarding the IOLs:

Serial Number	Model/Diopter	Product Location
		<input type="checkbox"/> Implanted <input type="checkbox"/> Previously Returned to B&L <input type="checkbox"/> Found & Placed On Hold <input type="checkbox"/> Could not find serial number
		<input type="checkbox"/> Implanted <input type="checkbox"/> Previously Returned to B&L <input type="checkbox"/> Found & Placed On Hold <input type="checkbox"/> Could not find serial number

Inventory has been checked and all subject product has been removed.

Product Found & Placed On Hold Was:

- Picked-up by B&L Representative on \_\_\_\_\_(date)
- Mailed to B&L on \_\_\_\_\_ (date).

\_\_\_\_\_  
**SIGNATURE of CUSTOMER**

\_\_\_\_\_  
**PRINTED NAME/TITLE**

\_\_\_\_\_  
**DATE**

**Please return completed form to:**

Fax: 888-912-2184

Email: Bauschandlomb5173@stericycle.com

**To Request Additional Shipping Labels:**

Phone: 866-556-1136

Email: Bauschandlomb5173@stericycle.com