AMO Ireland
Block B
Liffey Valley Office Campus
Quarryvale
Co.Dublin, Ireland

URGENT

FIELD SAFETY NOTICE

Product Recall

August X, 2016

Dear AMO Customer:

RE: FSN2016-02 Voluntary Recall of AMO Intraocular Lenses, Model Numbers; ZCB00, PCB00, AR40e, ZLB00, ZXR00

AMO is initiating this action due to detection of an inspection equipment malfunction that resulted in a total of 737 globally distributed lenses not being fully checked prior to release. It has been identified that this malfunction may result in the release of mislabeled IOLs. Use of a mislabeled IOL could lead to potential unexpected postoperative refractive error and may result in a secondary surgical intervention. Our records show that you were shipped IOLs impacted by this action.

We have pre-filled the attached Customer Reply Form with those specific IOL serial numbers on page 4.

The IOL serial number is displayed on the end of each individual unit carton (see page 3 for label example). The IOL serial number is also present on the IOL lens holder within the package.

Please undertake the following actions:

1. Compare your inventory against the attached list.
2. **STOP** using and remove from your inventory all **affected** IOLs listed in the attached Customer Reply Form.
3. Complete and return the attached Customer Reply Form **EVEN IF YOU HAVE NO INVENTORY** affected by this recall, to AMO Quality Assurance at ***[Insert regional fax number]*** or email to **[insert regional email address]** within **3 business days of receipt of this letter**. AMO requires this information for reconciliation purposes with regulatory agencies.

No other AMO IOLs are affected by this action. IOLs with serial numbers included in this letter that have been implanted and resulted in an appropriate post-op refractive outcome are not affected by this action.

This notice should be shared with anyone who needs to be aware within your organization or to any organization where the potentially affected products have been transferred.

If you have inventory of any of the IOLs with the serial number listed, please contact Customer Support at [insert regional contact number] to arrange pick up of lenses to be returned.

If you have product complaints or adverse events to report regarding the use of IOL, please inform AMO by calling *[Insert regional contact number].* If you do report a complaint, please provide the IOL serial number and, if a patient was involved, the date of surgery, a description of the event and patient outcome.

National Competent Authorities have been notified of this action.

This voluntary action reflects AMO's commitment to high quality standards and ensuring that our products fully meet your expectations. AMO remains fully committed to serving you and your patients with safe and effective products. We recognize the inconvenience this causes you and appreciate your assistance in expediting the return of this product.

Sincerely,

Michelle Hall

Senior Vigilance Specialist

AMO Ireland

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Ireland

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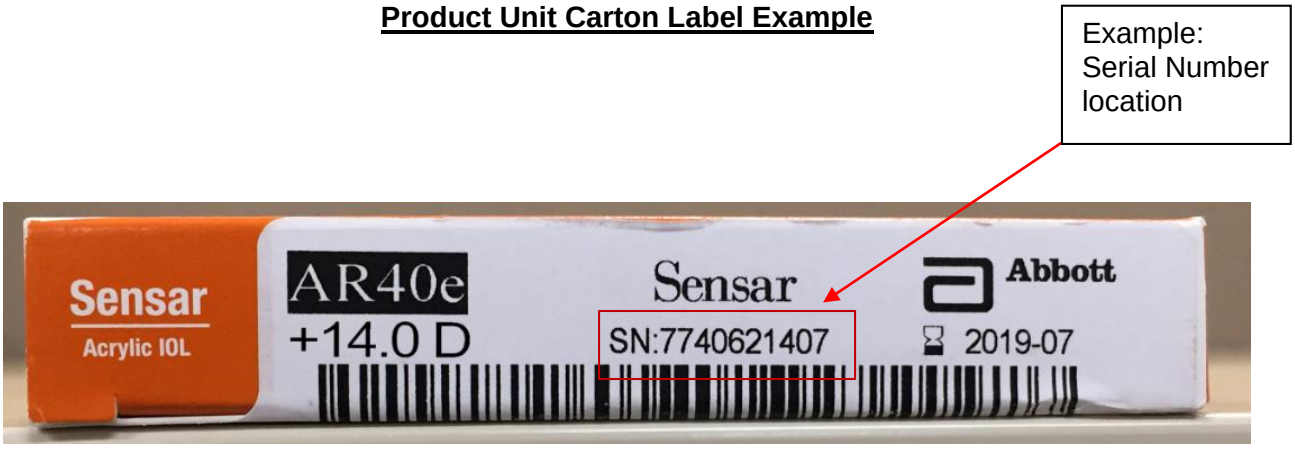
Product Unit Carton Label Example



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AMO Product RECALL Letter Dated August 26, 2016

AMO IOL RECALL CUSTOMER REPLY FORM

Please complete and return immediately EVEN IF YOU HAVE NO STOCK via Fax: *[fax number]* **or email:** *[Email address]*.

Please place an "X" in one of the boxes below.

☐ We have no stock of IOLs involved in the recall.

☐ All affected IOLs have been implanted or discarded.

☐ We are returning affected IOLs **RGA #** _____

Model	Serial Number	Status of IOLs (check one box for each serial number)		
		Implanted	Discarded	To be Returned

AMO Account Number:	
Account Name:	
Address:	
City, State, Zip Code	
Country	
Telephone Number:	

Person completing this form acknowledges the receipt and understanding of the actions, as stated in the Field Safety Notice:

Name: (print) _____

Title/Position _____

Signature: _____

Date: _____

Abbott
A Promise for Life