AMO Ireland
Block B, Liffey Valley Office Campus,
Quarryvale,
Dublin D22 XOY3
Ireland

URGENT

FIELD SAFETY NOTICE

April X, 2017

Dear AMO Customer:

RE: Voluntary Recall of Select Lots of AMO Healon OVDs

Abbott Medical Optics Inc. (AMO) is recalling 36 product lots of Healon OVDs of various models (this "**Action**"). **This Action only affects the Healon OVDs listed on page 4. No other AMO Healon OVD lots are affected by this Action.** The Healon OVD lot number is displayed on the end of each individual unit carton (see page 3 for label example). The OVD lot number is also present on each individual syringe packaging tray and each syringe.

AMO has voluntarily initiated this Action because a remote possibility exists that certain Healon OVD solutions in the affected lots may contain microscopic glass particles due to damage that occurred at the cylinder neck during the manufacturing process. Use of OVD solutions with glass particles could potentially lead to intraocular injury. **You are receiving this notice because our records indicate that you received Healon OVDs impacted by this Action**.

To date, no patient injuries have been reported in connection with any of the Healon OVDs impacted by this Action. Although no patient injuries have been reported and the probability of harm is considered remote, AMO believes this Action is in the best interests of patients and consistent with its commitment to product quality.

National Competent Authorities have been notified of this action.

Since you have received potentially affected product, please **immediately take the following actions**:

1. Compare your inventory against the attached list on page 4.
2. **STOP** using and remove from your inventory all **affected** OVD lots listed on page 4 of this letter. Note: You can continue to use all other lots not affected by this recall.
3. Complete and return the attached Customer Reply Form (page 5) **EVEN IF YOU HAVE NO INVENTORY** affected by this recall. AMO requires this information for reconciliation purposes with regulatory agencies.

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 OVDs with the lot number listed on page 4, please complete the Customer Reply Form, noting the lot numbers of the OVDs and contact Customer Support at *[Insert regional contact number]* to arrange pick up of affected OVD lots to be returned. Any returned product will be replaced.

The completed Customer Reply Form should be faxed 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**.

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

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

Block B

Liffey Valley Office Campus

Quarryvale

Dublin D22 XOY3

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Product Unit Carton Label Example

Example:

Lot Number location

EMEA Lot Numbers Affected By Recall per Model

Model	Lot No.
Healon	UB32514
Healon	UB32519
Healon	UB32522
Healon Pro	UB32524
Healon5 Pro	UB32526
Healon	UB32538
Healon	UB32574
Healon GV	UB32577
Healon	UB32579
Healon	UB32594
Healon GV	UB32597
Healon	UB32600
Healon	UB32604

AMO Product RECALL Letter Dated April X, 2017

AMO HEALON OVD 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.

☐ All affected products have been used.

☐ AMO Representative has returned all affected product inventory on our behalf.

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

Lot Number	Quantity of Healon OVD to be Returned	Lot Number	Quantity of Healon OVD 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: _____