

Abbott Medical Optics Inc.
1700 E. St. Andrew Place
Santa Ana, CA 92705

URGENT
FIELD SAFETY NOTICE

April 18, 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 Ophthalmic Viscosurgical Devices (OVDs) of various models (this “Action”). **This Action only affects the Healon GV OVDs listed on page 3. There was only affected one (1) affected lot was shipped to Singapore. No other AMO OVD lots are affected by this Action.** The Healon GV 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 GV 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.

Singapore HSA 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 3.
2. **STOP** using and remove from your inventory all **affected** OVD lots listed on page 3 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 4) **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 3, please complete the Customer Reply Form, noting the lot numbers of the OVDs and contact Customer Support at **(65)**

82882997 to arrange pick up of affected OVD lots to be returned. Returned product will not require refrigerated shipping. Any returned product will be replaced.

The completed Customer Reply Form should be faxed to AMO Singapore at **(65) 6844 8884** or email **boonpeng.nah@abbott.com** 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 **(65) 82882997**. 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,



Christopher Lim

Senior QA Manager

Asia Pacific & China Regional QA

Johnson & Johnson Vision, Surgical

cc Chairman Medical Board and relevant Head of Departments

Abbott Medical Optics, Inc. is now a member of the Johnson & Johnson Family of Medical Device Companies.

Product Unit Carton Label Example

Example:
 Lot Number
 location



Singapore Lot Numbers Affected By Recall per Model

Model	Lot No.
Healon GV	UB32576

OUS Lot Numbers Affected By Recall per Model

Model	Lot No.
HealonV	UB32491
Healon	UB32514
Healon	UB32519
Healon	UB32522
Healon Pro	UB32524
Healon5 Pro	UB32526
Healon	UB32533
Healon	UB32534
Healon	UB32536
Healon	UB32538
Healon	UB32573
Healon	UB32574
Healon GV	UB32576
Healon GV	UB32577
Healon	UB32579
Healon	UB32594
Healon GV	UB32597
Healon	UB32599
Healon	UB32600
Healon	UB32604
Healon	UB32614
Healon	UB32615
Healon	UB32616

AMO Product RECALL Letter Dated April 18, 2017

AMO HEALON OVD RECALL CUSTOMER REPLY FORM

**Please complete and return immediately EVEN IF YOU HAVE NO STOCK
via Fax: +66 2 219 2755 or email: boonpeng.nah@abbott.com**

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

<input type="checkbox"/>	All affected products have been used or discarded.	
<input type="checkbox"/>	AMO Representative has returned all affected product inventory on our behalf.	
<input type="checkbox"/>	We are returning affected products	RG# _____

Lot Number	Quantity of Healon OVD to be Returned
UB32576	

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: _____