

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,

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

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

Each mL of the Healon® OVD contains:
Sodium hyaluronate 5000 10 mg,
sodium chloride 8.5 mg,
disodium hydrogen phosphate dihydrate 0.28 mg,
sodium dihydrogen phosphate dihydrate 0.04 mg,
water for injection q.s.

For intraocular use.

Important!
This sterile, aseptically packaged syringe is sealed with a membrane which must be ruptured prior to use (see enclosed directions).

Caution, see instructions for use

See instructions for use

Do not reuse

Protect from freezing

Manufacturer

AMO Uppsala AB, Rappsgatan 7
Box 6406, SE-751 36 Uppsala, Sweden
Product of Sweden
Abbott Medical Optics Inc.
1700 E. St. Andrew Place
Santa Ana, CA 92705 USA
1-877-AMO-4-LIFE
www.amo-inc.com

Do not use if the packaging has been opened or damaged

2°C (36°F) 8°C (46°F)

Temperature limitation

Protect from light

Rx only

STERILE unless opened or damaged
LATEX FREE

Healon®

10 mg per mL
Sodium Hyaluronate

0.85 mL

Supplied with sterile single-use cannula

STERILE
Sterilized by ethylene oxide

STERILE
Sterilized using steam

Use by:

Abbott

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REF 10-2909-53

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 |

