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

URGENT

FIELD SAFETY NOTICE

April 19, 2017

Dear AMO Customer:

RE: Voluntary Recall of Two Lots of Vitrectomy Cutter

Abbott Medical Optics Inc. (AMO) is recalling 360 units of Vitrectomy Cutters from two (2) product lots (this "**Action**"). **This Action only affects the two (2) lots listed on page 4. No other AMO Vitrectomy Cutters are affected by this Action**. The lot number is displayed on the label attached to each package (see page 3 for label example).

AMO has voluntarily initiated this Action because a possibility exists that, due to a packaging error, 20GA Vitrectomy Cutters may be found in a 25GA package and 25GA Vitrectomy Cutters may be found in a 20GA package. Use of a Vitrectomy Cutter that is a different size than expected could lead to the need to alter the surgical technique, including conjunctival dissection, incision enlargement and scleral sutures. **You are receiving this notice because our records indicate that you received Vitrectomy Cutters impacted by this Action.**

To date, we have identified two (2) units of 20GA Vitrectomy Cutters in packaging labeled as 25GA.

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

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 the Vitrectomy Cutter, please inform AMO by calling *[Insert regional contact number].* If you do report a complaint, please provide the product 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 to providing you with products that 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.

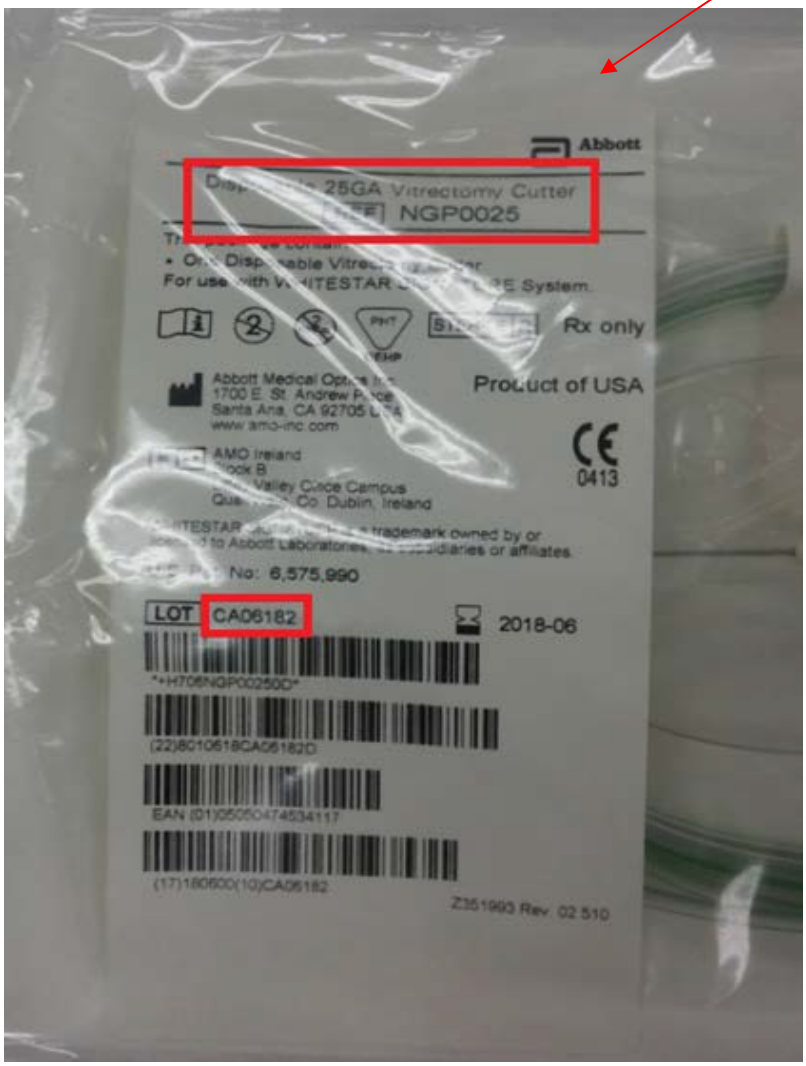
Sincerely,

_____

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

Product Unit Label Example

Example: Part Number and Lot Number location



Lot Numbers Affected By Recall per Part Number

Part Number	Description	Lot Number
NGP0020	20GA Vitrectomy Cutter and Irrigation Sleeve	CA06180

AMO Product RECALL Letter Dated April 19, 2017

AMO VITRECTOMY CUTTER 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 or discarded.

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

☐ We are returning affected product. **RGA #** _____

Lot Number	Quantity of Product 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: _____