Dear Customer:

This is to advise you of Allergan’s voluntary recall of fifteen (15) lots of XEN Glaucoma Treatment System (XEN 45 Gel Stent preloaded into a XEN® Injector). Our records indicate that you have received one or more shipments of the affected lots.

Refer to sections PRODUCT INFORMATION and RECALL INFORMATION for additional information about this recall.

The reason for recall, health assessment, and instructions for returning the affected product lots are given in the sections below. We ask that you follow our instructions in (1) responding to the recall notification and (2) returning the recalled merchandise.

Allergan has informed the U.S. Food and Drug Administration of this voluntary recall.

1. Upon receipt of this letter, please take the following actions:
   1. If you have inventory of the recalled products, quarantine product to prevent its use.
   2. Conduct a physical count of the affected products in your possession and record the count on the enclosed Business Reply Form (BRF).
   3. When returning the recalled product, attach the prepaid FedEx Authorized Return shipping label to the outside of the return carton. Return the recalled product and completed BRF to:
      Inmar Rx Solutions, Inc.
      4332 Empire Rd. Fort Worth, TX 76155
   4. If you have no recall product to return, please complete the BRF and return to Inmar Rx Solutions, Inc via fax or email within five (5) business days of receipt. To ensure we are able to account for all recalled product, it is imperative that you return the form. Please return the Reply Form even if no recalled product is present.
   5. Please Do Not return any products that are not the subject of this recall. Please contact Inmar Rx Solutions, Inc. if you have any questions about these recall actions.

Allergan began shipping this product on 01/19/2017.

Relevant sections:
- PRODUCT INFORMATION
- RECALL INFORMATION

Reason:
During in-process inspection, 4 (four) units in an unreleased XEN 45 lot were observed to have trace amounts of residual polishing compounds that are used in the needle sleeve manufacturing process. Explanting implanted devices is not being recommended; this recall is a retrieval of un-implanted inventory from affected lots. Please continue your routine post-operative follow up and report any adverse events to Allergan Product Surveillance.

Health Hazard Assessment:
The residual polishing compounds on the XEN® injector needle assembly could transfer to the patient’s eye during procedure possibly resulting in irritation, inflammation, local allergic reaction/ hypersensitivity, iritis, uveitis/sterile endophthalmitis or an intraocular foreign body. Signal detection review does not indicate an adverse trend associated with the residual polishing compounds.

Shipment information:
- Dates Distributed: 01/19/2017 - 09/06/2019
- Exp. Date: 11/30/2019
- Lot: 61650
- Dates Distributed: 03/10/2017 - 08/01/2019
- Exp. Date: 11/30/2019
- Lot: 61657
- Dates Distributed: 10/02/2017 - 05/28/2019
- Exp. Date: 01/31/2020
- Lot: 61779
- Dates Distributed: 08/09/2017 - 08/21/2019
- Exp. Date: 01/31/2020
- Lot: 61780
- Dates Distributed: 10/03/2017 - 09/11/2019
- Exp. Date: 01/31/2020
- Lot: 61825
- Dates Distributed: 08/09/2017 - 08/27/2019
- Exp. Date: 02/28/2020
- Lot: 61883
- Dates Distributed: 09/01/2017 - 09/06/2019
- Exp. Date: 02/28/2020
- Lot: 61884
- Dates Distributed: 12/18/2017 - 09/06/2019
- Exp. Date: 03/31/2020
- Lot: 61906
FDA contact information for reporting adverse events:
Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

We appreciate your cooperation in this product recall and regret the inconvenience this has caused you and your patients.

At Allergan, our first priority is to our customers and patients. We are committed to ensuring the safe and effective use of our products.

Thank you for your assistance in this matter.
Sincerely,
Allergan