FSN Ref: FSN-19-001-SG

FSCA Ref: FSCA-19-001

Date: 30-OCT-2019

Urgent Field Safety Notice
Allergan XEN Glaucoma Treatment System

Dear Healthcare Professional,

cc: Chairman Medical Board and relevant Head of Departments

Voluntary Recall of Allergan XEN Glaucoma Treatment System

During our inspection process a small number of units in an unreleased XEN 45 lot were observed to have trace amounts of polishing compounds that are used in the needle sleeve manufacturing process. Allergan has decided to conduct a voluntary recall of all LOTs of XEN Glaucoma Treatment System within expiry date in Singapore.

Our records indicate that you have received one or more shipments of XEN®. This recall is being conducted down to the Retail (Health Care Provider) Level.

It is important to note that removal of an implanted XEN® device is not being recommended; this recall is a retrieval of un-implanted inventory.

We understand this recall may cause an interruption to your practice and we apologize for the inconvenience it may cause you or your patients. We know you share our commitment to patient safety and appreciate your patience and understanding during this time.

For your reference, the lots that have been shipped to Singapore can be found below.

PRODUCT INFORMATION			
XEN® Glaucoma Treatment System (XEN® 45 Gel Stent preloaded into a XEN® Injector)			
Lot	**Expiry Date**	**Lot**	**Expiry Date**
61685	31 Dec 2019	62008	30 Apr 2020
61846	28 Feb 2020	62318	30 Nov 2020
61847	28 Feb 2020	62636	31 May 2021
61955	30 Apr 2020	62678	31 Jul 2021
61996	30 Apr 2020		

What has happened? 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.

Allergan Singapore Pte Ltd
Registration No.: 200312822D
20 Pasir Panjang Road,
Mapletree Business City
West Building, #09-25
Singapore 117439

T. (65) 6747 7077
F. (65) 6747 8289
www.allergan.com

FSN Ref: FSN-19-001-SG FSCA Ref: FSCA-19-001

What does this mean for my patients? 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.

To reiterate, removal of an implanted XEN® device is not being recommended; this recall is a retrieval of un-implanted inventory.

Please also note that patients who have undergone XEN® surgery do not require new or additional observation or procedures. Please continue your post-operative follow up regime for existing patients, as per local standard of care, and report any adverse events to MedDeviceComplaintsAPAC@Allergan.com.

What should I do if I have a patient that presents with symptoms? In the unlikely event of an adverse reaction due to the issue identified here, signs and symptoms of greater than anticipated anterior segment inflammation will manifest within hours of surgery and be detected by the surgeon during routine early postoperative follow up and their management can be initiated promptly. The treatment guidelines for such events are well established and should be followed meticulously. We ask you report all such events to MedDeviceComplaintsAPAC@Allergan.com immediately.

What happens next?

Upon receipt of this letter, please take the following actions:

1. Customers/Physicians should identify if you have inventory of the recalled product, and immediately quarantine the 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 Response Form (BRF).
3. As acknowledgement of the receipt of this FSN, please return the BRF to Allergan Sales and Marketing Manager (SeoTho WeeSian) via fax +65 6747 8289 or email [redacted] 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 BRF even if no recalled product is present.**
4. If you have any inventory of the affected products indicated in your returned BRF, a customer service representative will be in contact with you to help process the return.

Please contact Allergan Sales and Marketing Manager (SeoTho WeeSian) [redacted] if you have any questions about these recall actions.

Allergan Singapore Pte Ltd
Registration No.: 200312822D
20 Pasir Panjang Road,
Mapletree Business City
West Building, #09-25
Singapore 117439

T. (65) 6747 7077
F. (65) 6747 8289
www.allergan.com

FSN Ref: FSN-19-001-SG FSCA Ref: FSCA-19-001

Where can I get more information? For more information please contact Allergan Medical Information at +65 3158 0552 or email medinfo.singapore@allergan.com. Patients can also report adverse events directly to Allergan Product Surveillance by (Toll-free) 800-101-3387, (DID) 0011-424-3014-709, or emailing MedDeviceComplaintsAPAC@Allergan.com.

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.

Sincerely,

[redacted]

How Hee Loong (Mr)
Business Unit Head - Eyecare
Allergan

Allergan Singapore Pte Ltd
Registration No.: 200312822D
20 Pasir Panjang Road,
Mapletree Business City
West Building, #09-25
Singapore 117439

T. (65) 6747 7077
F. (65) 6747 8289
www.allergan.com

Allergan

BUSINESS REPLY FORM

Date: October 30, 2019

Allergan XEN Glaucoma Treatment System

We kindly ask you to complete this form and return it by e-mail to Allergan Sales and Marketing Manager (SeoTho WeeSian) via fax +65 6747 8289 or email [redacted] within five (5) business days of receipt.

Affected Product:
XEN® Glaucoma Treatment System (XEN® 45 Gel Stent preloaded into a XEN® Injector)
(Please refer to the FSN for the affected lots that have been shipped to Singapore)

I certify that
- I have received the Field Safety Notice (FSN) for the Allergan XEN Glaucoma Treatment System and distributed it to the appropriate people in my facility.
- I have verified the presence in stock in my establishment of the products concerned by this action

Tick the appropriate proposal and indicate the number of devices identified:

☐ We have products concerned by the recall in stock. We request that Allergan Customer Service contact us to coordinate the return of items in our possession. Please indicate below the lot numbers and quantities in stock, if necessary, please attach a list with these data.

Lot number	Quantity in stock

☐ We no longer have any recalled products in stock and will not make any returns.

Customer name			
Contact name			
Address			
Telephone number			
Signature		**Date :**	

Allergan Singapore Pte Ltd
Registration No.: 200312822D
20 Pasir Panjang Road,
Mapletree Business City
West Building, #09-25
Singapore 117439

T. (65) 6747 7077
F. (65) 6747 8289
www.allergan.com