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

Date: 30-OCT-2019

Urgent Field Safety Notice
Allergan XEN Glaucoma Treatment System

For Attention of*:All Healthcare Professionals holding stock of Allergan XEN Glaucoma Treatment System

Contact details of local representative (name, e-mail, telephone, address etc.)*
Nina Labhart Meuli **Email: Labhart_Nina@allergan.com / quality.switzerland@allergan.com** **Address:** **Allergan AG** **Puls 5** **Hardturmstr. 11** **CH-8005 Zürich** **Switzerland** **Tel. +41 44 204 23 00 (Zentrale)** **Tel. +41 204 23 12 (Direkt)** **Tel. +41 79 592 0580 (Mobile)**

Weitere Kontaktangaben:

Verkauf	**Medizinische Anfragen**	**Kundendienst**
Isabelle Blanchet National Sales Manager Tel: +41 79 909 94 75 e-mail: Isabelle.Blanchet@allergan.com	Medical Information Tel: 0800 007 124 Email: medinfo.switzerland@allergan.com	Customer Service Tel: 0800 111 239 (deutsch) 0800 111 238 (französische) Email: CS_Alpine@allergan.com
Geschäftsleitung	**Qualitätssicherung**	
Sabine Stadie Geschäftsführerin Schweiz und Österreich Tel: 044 204 23 00 Email: stadie_sabine@allergan.com	**Nina Labhart Meuli** QA Manager Tel: 044 204 23 12 Email: quality.switzerland@allergan.com	

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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.

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	XEN® Glaucoma Treatment System consists of a XEN® Gel Stent preloaded into a XEN® Injector .
1.	2. Commercial name(s)
	XEN Glaucoma Treatment System
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The XEN® Gel Stent is intended to create a channel through the sclera allowing flow of aqueous humor from the anterior chamber into the subconjunctival space to reduce intraocular pressure (IOP).
1.	5. Device Model/Catalogue/part number(s)*
	5507-001
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	All LOTs within expiry (61566, 61580, 61626, 61642, 61685, 61846, 61847, 61955, 61996, 62008, 62031, 62053, 62066, 62108, 62130, 62263, 62297, 62318, 62380, 62636, 62678, 62719, 62749)
1.	8. Associated devices
	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	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.
2.	2. Hazard giving rise to the FSCA*
	Trace amounts of polishing compounds on the XEN® injector needle could transfer to patient's eye during procedure possibly resulting in irritation, inflammation, local allergic reaction/ hypersensitivity, iritis, uveitis/sterile endophthalmitis or an intraocular foreign body.
2.	3. Probability of problem arising
	No confirmed occurrences have been reported related to this issue in EU. Signal detection review does not indicate an adverse trend associated with this issue. This recall is considered a precautionary activity.
2.	4. Predicted risk to patient/users
	The overall risk of harm is moderate.
2.	5. Further information to help characterise the problem
	N/A
	6. Background on Issue

2.	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.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately.
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Based on the available information, Allergan is not recommending explantation of implanted XEN Gel Shunts or any change to current practice.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Withdrawal of all LOTs within expiry of Allergan XEN Glaucoma Treatment System. No action with regards to already implanted devices.	
3	6. By when should the action be completed?	Immediately
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN-19-001 22-OCT-2019
4.	**3.** For Updated FSN, key new information as follows:	
	All LOTs within expiry now added.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Allergan**
	b. Address	**2525 Dupont Drive, Irvine, CA 92612, USA**
	c. Website address	**www.allergan.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	
4.	10. Name/Signature	

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Appendix 1: Returns and Receipt Form

Response form Field Safety Note (FSN)
FSN-19-001

Date: October 30, 2019

Allergan XEN Glaucoma Treatment System

We kindly ask you to complete this form and return it by e-mail to **quality.switzerland@ALLERGAN.com** (form completed in PDF format) within seven (7) working days.

Medical devices implantable by this communication:

- **Allergan XEN Glaucoma Treatment System, catalogue number 5507-001**

I certify that
- I have received the Field Safety Note (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 batch numbers and quantities in stock, if necessary, please attach a list with these data.

Batch number	Serial no.	Quantity in stock

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

Client's name			
Contact name			
Address			
Telephone number			
Signature		**Date :**	