



URGENT FIELD SAFETY NOTICE

RECALL

FSCA N° 19-002

Date: February 3, 2020

To the attention of the end-users and distributors of the following products:

Product code S5.7160

Designation: Purified silicone oil, syringe 15 mL – 1000 cSt

Batch numbers:

1900768	1901325	1901615	1901929	1902017	1902234
---------	---------	---------	---------	---------	---------

Product code S5.7170

Designation: Purified silicone oil, syringe 10 mL – 1000 cSt

Batch numbers:

1900766	1901122	1901124	1901252	1901282	1901283	1901956
---------	---------	---------	---------	---------	---------	---------

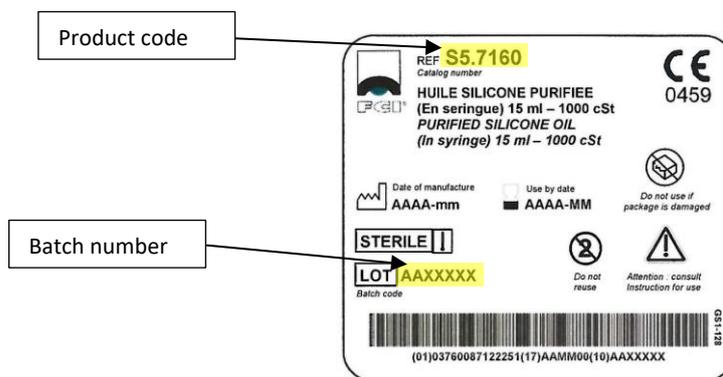
Product code S5.7560

Designation: Purified silicone oil, syringe 15 mL – 5000 cSt

Batch numbers:

1901641

See below product label for ease in identifying the product at the user level.



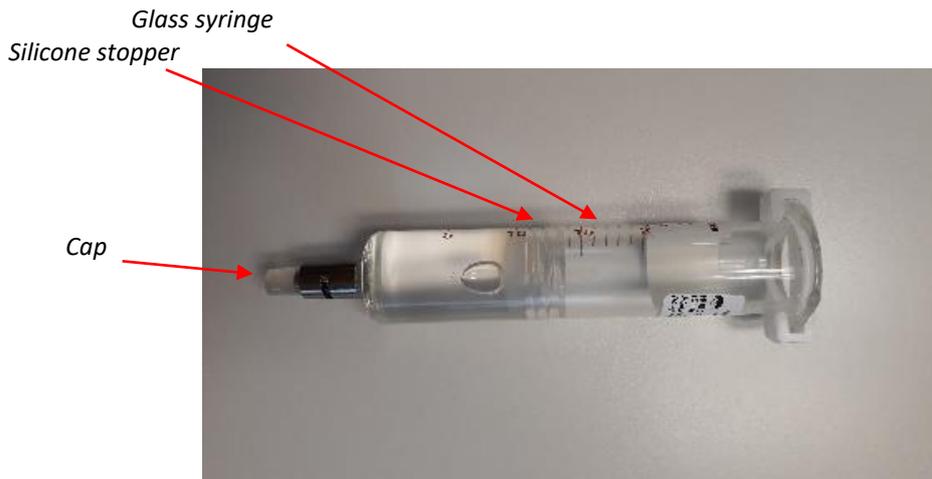
Type of action taken by the manufacturer:

- Recall
- Correction
- Destruction
- Instruction

FSCA N° 19-002

Dear customer,

The products mentioned above are glass syringes which contain silicone oil. A silicone stopper is inserted into the syringe to preserve the oil from contamination, and of course to enable the future injection in the patient's posterior chamber by pushing forward the silicone oil.



FCI S.A.S. has received a customer complaint regarding a difficulty or even impossibility to inject the silicone oil, with or without an unusual position of the stopper in the syringe.

After analysis, it appears that this problem is due to a lack of lubrication of the stopper's periphery before it is inserted into the syringe during manufacture.

This lubrication allows the stopper to be easily inserted into the syringe and pushed towards its end when the user applies pressure to inject the oil.

Defect leading to the FSCA:

Due to the lack of lubrication of the stopper, we have noticed a strong adherence to the inner wall can occur. It may also twist slightly during autoclave sterilization of the device. In both cases, the silicone oil can be difficult or even impossible to inject.

Probability of the problem occurring:

To date, FCI S.A.S. records an occurrence rate for this problem of 0.049%

Risk for patients/users:

Following an internal patient risk analysis, FCI S.A.S. has identified the following risks for the patient:

- Longer operating time due to the difficulty or even impossibility of injecting silicone oil
- For manual injections with plunger only: if the syringe cannula is positioned into the trocar on the patient's eye, and the injection resistance causes the surgeon to apply significant manual pressure on the syringe, it may lead to increased pressure of the trocar cannula against the surrounding tissues, possibly creating slight damage to the conjunctiva/sclera.

No risk has been identified for users.



Recommendations for users:

Immediately proceed with the following steps:

- Immediately examine your inventory. Identify the concerned products in your stock and stop using them. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall letter.
- Count the products which have been used.
- Fill in and return page 6 of this document, and contact the Quality department by fax (+33 (0)3 81 88 39 28) or by email (qualite@fci.fr) to get the return instructions of the unused devices still in your possession.

Transmission of this FSN:

This notice must be forwarded to anyone who must be informed within your organization or to any other third party potentially concerned.

To ensure the effectiveness of this corrective action, this information must be maintained until the stocks of the above-mentioned batches are sold out.

In order to be sure that this Safety Notice has been well received, please kindly return the acknowledgment receipt below, after signature.

Please note that the competent Irish authority (HPRA) has been informed of this notification.

Rest assured that maintaining a high security and quality of our products is our priority. If you have any further question, do not hesitate to immediately contact us:

Mrs. GALLARD or Mr. BOUJEDLI: FCI S.A.S. Material-vigilance correspondents.

2 Rue Carl Zeiss
25000 Besançon
FRANCE

Phone Mrs. GALLARD: +33 (0)3 81 84 72 35 / +33 (0)6 49 09 90 48

Phone Mr. BOUJEDLI: +33 (0)3 81 84 72 30 / +33 (0)6 29 13 87 45

Mr Rachid BOUJEDLI

Quality & Regulatory Affairs Director

February 3, 2020



Acknowledgment of receipt FSCA Nr. 19-002

Quantity sold by FCI: _____, dated _____

FCI S.A.S. Product code	Designation	Batch number	Quantity shipped by FCI S.A.S.	Quantity in your possession	Quantity already used
S5.7160	Purified silicone oil, syringe 15mL – 1000 cSt	1900768	15		
		1901325	6		
		1901615	6		
		1901929	4		
		1902017	18		
		1902234	15		
S5.7170	Purified silicone oil, syringe 10mL – 1000 cSt	1900766	18		
		1901122	8		
		1901124	3		
		1901252	12		
		1901282	2		
		1901283	14		
		1901956	29		
S5.7560	Purified silicone oil, syringe 15mL – 5000 cSt	1901641	5		

To: Mrs. GALLARD and Mr. BOUJEDLI, Material-vigilance correspondents.

Email: qualite@fci.fr

Organization:

Name:

Function:

Email:

Hereby, we confirm that we have well received and read this Field Safety Notice and that we have forwarded it to the concerned people.

Date and Signature: