



URGENT FIELD SAFETY NOTICE

FSCA N° 19-002

Date : December 13th, 2019

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

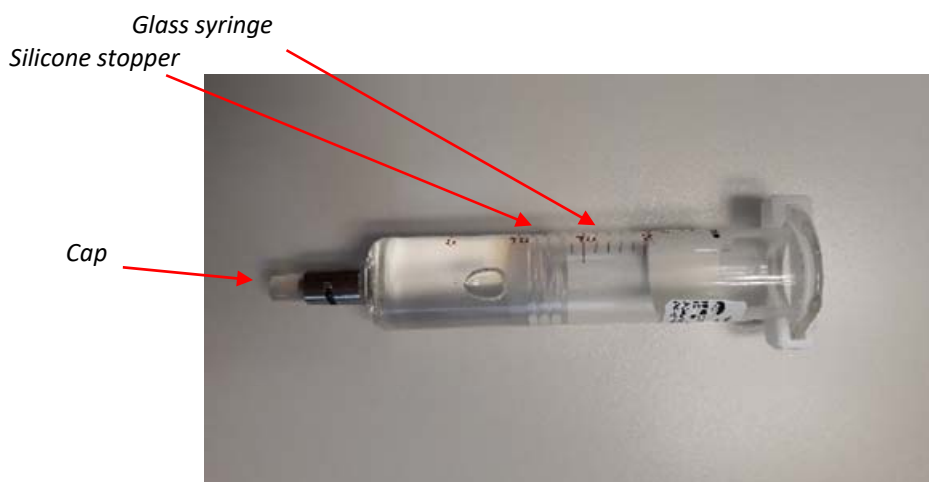
FCI S.A.S. product codes	Commercial name
S5.7570	Purified silicone oil – syringe 10 ml 5000 cSt - par1
S5.7170	Purified silicone oil – syringe 10 ml 1000 cSt - par1
S5.7560	Purified silicone oil – syringe 15 ml 5000 cSt - par1
S5.7160	Purified silicone oil – syringe 15 ml 1000 cSt - par1

Type of action taken by the manufacturer

- Recall
- Correction
- Destruction
- Instruction**

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.

Danger 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 0.013%

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.

Batch numbers concerned by this incident in France:

S5.7160	S5.7560
1900768	1901641
1901125	
1901251	
1901324	
1901325	
1901615	
1901929	
1902017	

Batch numbers concerned by this incident out of France:

S5.7160	S5.7170	S5.7560	S5.7570	
1900768	1900502	1901641	1900206	1901078
1901125	1900503		1900207	1901079
1901251	1900765		1900208	1901080



S5.7160	S5.7170	S5.7560	S5.7570	
1901324	1900766		1900369	1901081
1901325	1901122		1900370	1901117
1901615	1901123		1900371	1901118
1901929	1900767		1900463	1901119
1902017	1901121		1900464	1901120
	1901124		1900465	1901213
	1901252		1900468	1901214
	1901284		1900467	1901315
	1901323		1900573	1901316
	1901283		1900574	1901317
	1901282		1900575	1901348
			1900466	1901593
			1900572	1901594
			1900975	1901595
			1900802	1901596
			1900803	1901639
			1900804	1901708
			1900918	1901640
			1900919	1901318
			1900920	1901349
			1900921	1901360
			1900922	1901361
			1900923	1901362
			1900971	1901363
			1900972	1901364
			1900973	1901365
			1900974	1901366
			1900976	1901367
			1900977	1901350
			1900978	1901351
			1900941	1901352
			1900942	1901353
			1900943	1901354
			1900944	1901355
			1900945	1901356
			1900946	1901357
			1901211	1901359
			1901210	1901986
			1901212	1902189
			1901076	1902190
			1901077	

Recomendations for the users :

In order to eliminate any risk of clinical consequences for the patient, FCI recommends following the procedure below before using the device on the patient.

- Open the pouch containing the syringe
- Visually check the position of the stopper

o If the stopper is not correctly positioned (as shown in the picture below):

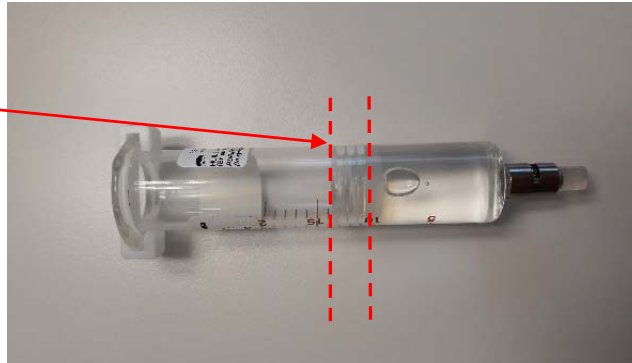


- Grasp the piston in the pouch and insert it into the syringe
- Screw the piston into the stopper
- Remove the cap from the end of the syringe
- Use the piston to apply a force on the stopper, so that it is repositioned and then on the piston to check that the stopper slides easily into the syringe and that the oil comes out of the syringe. In this case, the device can then be used on the patient.



- o If the stopper is correctly positioned (as shown on the picture below):

The stopper is perpendicular to the syringe



Proceed with the normal use of the syringe and check the silicone oil is normally flowing out.

If the silicone oil does not normally flow out, proceed with the following steps:

- Grasp the piston in the pouch and insert it into the syringe
- Screw the piston into the stopper

Piston screwed into the stopper



- Remove the cap from the end of the syringe
- Press the piston to activate the stopper and check if it slides easily into the syringe.
 - If the stopper slides easily into the syringe and the oil comes out of the syringe, the syringe can be used on the patient without any problem.
 - If the stopper has resistance and difficulty moving, then apply force on the stopper with the piston to unlock it and then use the device on the patient.

Transmission of this FSN:

This notice must be forwarded to anyone who has to 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 or receipt below, after signature.



Please note that the competent French authority (ANSM) 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

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

*Manuella GALLARD
Product Quality Assurance Supervisor
December 16th, 2019*



Acknowledgment of receipt FSCA Nr. 19-002

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S5.7160	Purified silicone oil – syringe 15 ml 1000 cSt - par1

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: