FLUORON®

Urgent safety information

Voluntary batch recall
regarding

Product	**Siluron® 1000**
Article Nummer	G-80720
Variant	Syringe
Lot no Expiry date UDI	Sil1 10S 120523 2028-04 042601604512272804305il110S120523
Lot no Expiry date UDI	Sil1 10S 170523 2028-04 042601604512272804305il110S170523
Product	**Siluron® 2000**
Article Nummer	G-80740
Variant	Syringe
Lot no Expiry date UDI	SIL2 10S 190623 2026-05 042601604514182605315il210S190623
Lot no Expiry date UDI	SIL2 10S 180723 2028-06 042601604514182806305il210S180723

Product	**Siluron® Xtra**
Article Nummer	G-80750
Variant	Syringe
Lot no Expiry date UDI	SILX 10S 020623 2026-05 042601604515172605315ilX10S020623

Manufacturer	**Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)**

To whom it may concern,

You have received from us silicone oil of the type Siluron® 1000, Siluron® 2000 and Siluron® Xtra. This letter is to inform you that in some cases cloudiness has been observed after injection in the following batches:

Product	**Article**	**Lot no**
Siluron® 1000	G-80720	Sil1 10S 120523 Sil1 10S 170523
Siluron® 2000	G-80740	SiL2 10S 190623 SIL2 10S 180723
Siluron® Xtra	G-80750	SILX 10S 020623

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The opacity presents as a temporary limitation of the patient's vision. The oil looks cloudy in the eye. Droplets as in emulsification cannot be observed.

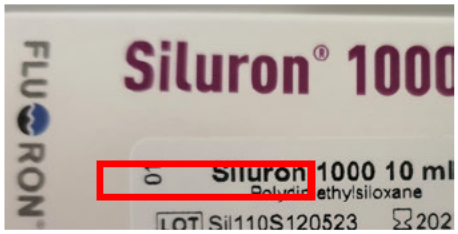
The opacity has no effect on the function of the silicone oil as a tamponade of the retina. Toxic effects or inflammation have not been reported. The patient's temporary visual limitation remains until the product is explanted and disappears as soon as the oil is removed.

The cause of this is currently being investigated. The chemical, physical and biological tests have shown that the oil meets the specifications.

As a precaution, however, we ask you to take the following measures:

- Block the products of these batches that you have on your premises.
- Do not continue to use the batches mentioned in these letters.
- Premature intervention is not recommended based on the data currently available to us. Should the user decide to do so, we recommend further treatment e.g., with Siluron® 5000.
- Please inform your distributors and end users about this safety information and confirm this to us within 10 days of receipt of this letter.
- Please ensure consumption, destruction or return of the products to us and confirm this to us within 33 days of receipt of this letter.

The batch number can be seen on the closure label:



We apologise for the inconvenience and thank you for your support.

If you have any questions, please contact:

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D-89077 Ulm
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Tel.: [redacted]

[redacted]
Plant Manager, PRRC
FLUORON GMBH