

Urgent safety information

**Voluntary batch recall
regarding**

Product	Siluron® 1000
Article Nummer	G-80720
Variant	Syringe / <i>Sprøjte</i>
Lot no	Sil1 10S 120523
Expiry date /udløbsdato	2028-04
UDI	04260160451227280430Sil110S120523
Lot no	Sil1 10S 170523
Expiry date / Udløbsdato	2028-04
UDI	04260160451227280430Sil110S170523

Product	Siluron® 2000
Article Nummer	G-80740
Variant	Syringe / <i>Sprøjte</i>
Lot no	SIL2 10S 190623
Expiry date /udløbsdato	2026-05
UDI	04260160451418260531Sil210S190623
Lot no	SIL2 10S 180723
Expiry date / Udløbsdato	2028-06
UDI	04260160451418280630Sil210S180723

Product	Siluron® Xtra
Article Nummer	G-80750
Variant	Syringe / <i>Sprøjte</i>
Lot no	SILX 10S 020623
Expiry date /udløbsdato	2026-05
UDI	04260160451517260531SilX10S020623

Manufacturer /Leverandør	Fluoron GmbH, Magirus-Deutz-Str. 10, 89077 Ulm (DE)
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To whom it may concern,
Til rette personer,

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:

I har modtaget fra os Silicone olie af typen Siluron 1000, Siluron 2000, og Silorun Xtra. Med dette brev informerer vi om at der kan i få tilfælde har været observeret skygger på patienten efter injektion i følgende 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

FLUORON® GmbH
Gesellschaft für hochreine Biomaterialien
Company Headquarters
89077 ULM, GERMANY
General manager: Volker Geuder
Registered in Ulm HRB 723852
VAT No.: DE812135435

phone: +497312055997-0
fax: +49731205599728
info@fluoron.de
www.fluoron.de

Commerzbank AG, Ulm
Account No. 08 011 588 00
Bank Code: 630 800 15
SWIFT-BIC: DRES DE FF630
IBAN: DE56630800 150801158800

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.

Opaciteten viser sig som en midlertidig begrænsning af patientens syn. Olien ser uklart ud i øjet. Dråber som ved emulgering kan ikke observeres.

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.

Opaciteten har ingen indflydelse på silikoneoliens funktion som tamponade af nethinden. Toksiske virkninger eller betændelse er ikke blevet rapporteret. Patientens midlertidige synsbegrænsning forbliver, indtil produktet eksplanteres og forsvinder, så snart olien fjernes.

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

Årsagen til dette er i øjeblikket ved at blive undersøgt. De kemiske, fysiske og biologiske test har vist, at olien lever op til specifikationerne.

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

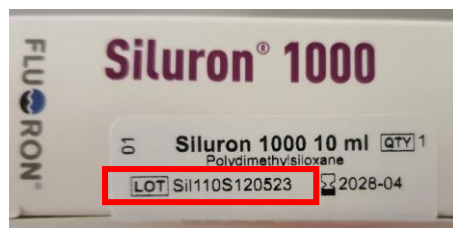
- Block the products of these batches that you have on your premises.
- Do not continue to use the batches mentioned in these letters.
- Premature intervention is not recommended based on the data currently available to us. Should the user decide to do so, we recommend further treatment e.g., with Siluron® 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.

For en sikkerheds skyld beder vi jer dog tage følgende forholdsregler:

- *Bloker produkterne fra disse partier.*
- *Fortsæt ikke med at bruge batches nævnt i dette brev.*
- *For tidlig indgriben anbefales ikke baseret på de data, som er tilgængelige for os i øjeblikket. Hvis brugeren beslutter sig for at gøre det, anbefaler vi yderligere behandling, f.eks. med Siluron® 5000.*
- *Informér venligst dine distributører og slutbrugere om disse sikkerhedsoplysninger og bekræft dette over for os inden for 10 dage efter modtagelsen af dette brev.*
- *Sørg for forbrug, destruktions eller returnering af produkterne til os og bekræft dette over for os inden for 33 dage efter modtagelsen af dette brev.*

The batch number can be seen on the closure label:

Batchnummeret kan ses på lukkeetiketten:



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

Vi undskylder for ulejligheden og takker for jeres hjælp.

If you have any questions, please contact:

Såfremt der er yderligere spørgsmål, må i endelig kontakte os:

FLUORON® GmbH
Gesellschaft für hochreine Biomaterialien
Company Headquarters
89077 ULM, GERMANY
General manager: Volker Geuder
Registered in Ulm HRB 723852
VAT No.: DE812135435

phone: +497312055997-0
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IBAN: DE56630800 150801158800



Complaint@Fluoron.de

or

Fluoron GmbH
- Markus Manger -
Magirus-Deutz-Straße 10
D-89077 Ulm
GERMANY

Tel.: + 49 731 2055997 22

Yours sincerely,

A handwritten signature in blue ink, appearing to be "Manger", written over a horizontal dotted line.

ppa. Markus Manger
Plant Manager, PRRC
FLUORON GMBH

FLUORON®GmbH
Gesellschaft für hochreine Biomaterialien
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