Summary of Safety and Clinical Performance (SSCP)

Device group: Siluron®
Devices: Siluron® 1000, Siluron® 2000, Siluron® Xtra and Siluron® 5000
in accordance with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1. Device trade name(s)

Siluron® 1000, Siluron® 2000, Siluron® Xtra and Siluron® 5000

1.2. Manufacturer's name and address

Fluoron® GmbH
Gesellschaft für hochreine Biomaterialien
Magirus-Deutz-Straße 10
89077 Ulm
Germany
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1.3. Manufacturer's single registration number (SRN)

DE-MF-000009235

1.4. Basic UDI-DI

4260160455105G

1.5. Medical device nomenclature description / text

CND Q02030202, OPHTHALMIC SURGERY, SILICONE OILS
GMDN 45125, Retinal tamponade medium, postoperative

1.6. Class of device

The product group silicone oil consists of surgically invasive medical devices that are used postoperatively as long-term tamponade and are classified as class IIb products.

1.7. Year when the first certificate (CE) was issued covering the device

Product	Year
Siluron® 1000	2002
Siluron® 2000	2008
Siluron® 5000	2002
Siluron® Xtra	2013

1.8. Authorised representative if applicable; name and the SRN

DE-MF-000009235

1.9. NB's name (the NB that will validate the SSCP) and the NB's single identification number

BSI Netherlands
Say Building, John M. Keynesplein 9
1066 EP Amsterdam, Netherlands
Identification Number of the Notified Body: 2797

2. Intended use of the device

2.1. Intended purpose

Siluron® 1000 / 2000 / Xtra / 5000 are sterile medical devices composed of ultrapure silicone oil (polydimethylsiloxane). Siluron® 1000 / 2000 / Xtra / 5000 are used as postoperative long-term endotamponades in the field of ophthalmic surgery.

2.2. Indication(s) and target population(s)

Siluron® 1000 / 2000 / Xtra / 5000 are intended only for ocular application. Siluron® 1000 / 2000 / Xtra / 5000 are used for the treatment of severe cases of retinal detachment, especially for:

- Retinal detachments with giant tears
- Retinal detachments with proliferative vitreoretinopathy (PVR)
- Retinal detachments in cases of proliferative diabetic retinopathy (PDR)
- Traumatic retinal detachments

Siluron® 1000 / 2000 / Xtra / 5000 is also used as a tamponade in macular hole surgery.

Intended patient population: Patients requiring surgical treatment of severe retinal detachment or surgical treatment of a macular hole. Use in pregnant women, nursing mothers, and children is not recommended.

2.3. Contraindications and/or limitations

Siluron® 1000 / 2000 / Xtra / 5000 are not permitted to be used in patients who are hypersensitive to silicone oil or wear a silicone intraocular lens (IOL). In addition, laser coagulation or cryotherapy are not permitted in eyes filled with Siluron® 1000 / 2000 / Xtra / 5000.

3. Device description

3.1. Description of the device

Siluron® 1000/2000/Xtra/5000 are sterile colourless, homogeneous liquids that consist of ultrapure polydimethylsiloxane. They contain no biologically active components, are chemically and physiologically inert, and non-toxic.

Siluron® 1000/2000/Xtra/5000 is used as a long-term tamponade for the treatment of severe cases of retinal detachment, especially for retinal detachments with giant tears, retinal detachments with proliferative vitreoretinopathy, retinal detachments in cases of proliferative diabetic retinopathy or traumatic retinal detachments. Siluron® 1000/2000/Xtra/5000 is also used as a tamponade in macular hole surgery.

For this purpose, the medical device is injected into the vitreous cavity of the eye for invasive surgical applications in accordance with its intended use. With the exception of eyes having a complex baseline situation, the indwelling time for Siluron® 1000/2000/Xtra/5000 should be kept as short as possible and limited to at most 6 months. A short length of indwelling time can reduce potential side effects and complications.

Siluron® 1000/5000 are well-established devices that have been in use since August 2002. Siluron®2000 was CE certified in October 2008 and is marketed since 2009. Siluron® Xtra has been approved in 2013 and is marketed since then.

Polydimethylsiloxane is commonly used in retinal surgery and belongs to chemical compounds referred as silicone oils. The polymer consists of silicone and oxygen atoms linked by single covalent bonds. Two methyl groups are attached to each silicon atom on this polymer backbone. The structural formula of polydimethylsiloxane is $(CH_3)_3SiO\text{-}[Si(CH_3)_2O]_n\text{-}Si(CH_3)_3$. Silicone oil is an optically clear, viscous, hydrophobic, and lipophilic liquid with a refractive index of 1.39 – 1.40 at 35°C. It is lighter than water (density 940 – 980 kg/m³ at 35°C) and oxygen permeable. Silicone oil has a high surface tension against air and water and as a result will not mix with both either. While these physical properties are applicable for all Siluron® oils (Siluron® 1000, Siluron® 5000, Siluron® 2000 and Siluron® Xtra), the viscosity depends on the length of the polydimethylsiloxane chain, i.e. the number of repeating siloxane units or the molecular weight, respectively.

Siluron® silicone oils can be subdivided into the standard Siluron® 1000 and 5000 (named according to their approximate viscosity of 1,000 and 5,000 mPas, respectively) and the oil blends Siluron® 2000 and Xtra. Siluron® 2000 consists of 95% Siluron® 1000 and 5% of a long chain high molecular weight (HMW) silicone oil of about 2.5 Mio mPas (Siluron Xtra: 90% Siluron® 1000 and 10% HMW silicone oil, 2.5 Mio mPas). By adding 10% silicone oil with 423 kDa, the shear viscosity of Siluron®Xtra doubles to mean values of around 4,437 mPas (at 25 s^{-1}) as compared to Siluron® 2000 with 2,213 mPas (mean value at 25 s^{-1}). However, this value is lower than the shear viscosity of the 5,000 mPas silicone oil with e.g. 5,052 mPas. This provides Siluron® 2000 and Siluron® Xtra with a high resistance to emulsification compared to standard silicone oils like Siluron® 1000 and 5000 while maintaining good applicability.

Property	Siluron® 1000	Siluron® 5000	Siluron® 2000	Siluron® Xtra
Composition, Substances in contact with the patient's tissues	Polydimethylsiloxane Structural formula: $(CH_3)_3SiO$-$[Si(CH_3)_2O]_n$-$Si(CH_3)_3$			
Density [kg/m³, 35 °C ± 2 °C]	940 – 980			
Dynamic Viscosity [mPas, 25 °C ± 2 °C]	900 – 1,200	4,600 – 5,600	1,800 – 2,400	4,100 – 5,000
Dynamic Viscosity [mPas, 35°C ± 2 °C]	650 – 980	3,700 – 4,700	1,500 – 2,000	3,400 – 4,200
Refractive index [35 °C ± 2 °C]	1.398 – 1.402			
Dosage form	The sterile medical devices Siluron® 1000/2000/Xtra/5000 are available in 10-mL glass vials and glass syringes. Vials and syringes are only intended for single use on one patient.			
Sterilisation method	Dry heat sterilization for the product and steam sterilisation for the packaging.			
Other informations	The medical devices Siluron® 1000/2000/Xtra/5000 do not contain any medical substances or derivatives of human blood or plasma. The medical devices Siluron® 1000/2000/Xtra/5000 do not contain tissue(s) or cells of human or animal origin or their derivatives. The medical devices Siluron® 1000/2000/Xtra/5000 do not contain substances or combinations of substances that are absorbed by or locally dispersed in the human body. The medical devices Siluron® 1000/2000/Xtra/5000 do not contain CMR (carcinogenic, mutagenic or toxic to reproduction) substances or endocrine-disrupting substances.			

3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences

There is no predecessor device to Siluron® 1000/5000. However, Siluron® 2000 and Siluron® Xtra were introduced later to the market in order to provide higher-viscosity silicone oils with a lower emulsification tendency while maintaining good injectability.

Product	Variants
Siluron® 1000	Polydimethylsiloxane Viscosity [mPas, 25°C ± 2°C]: 900-1200 mPas
Siluron® 2000	Polydimethylsiloxane Viscosity [mPas, 25°C ± 2°C]: 1800-2400 mPas
Siluron® 5000	Polydimethylsiloxane Viscosity [mPas, 25°C ± 2°C]: 4600-5600 mPas
Siluron® Xtra	Polydimethylsiloxane Viscosity [mPas, 25°C ± 2°C]: 4100-5000 mPas

No major changes have been made to Siluron® 1000/2000/Xtra/5000 silicone oil medical devices since their CE mark registration, respectively.

3.3. Description of any accessories which are intended to be used in combination with the device

No specific accessories are necessary for the application of Siluron® 1000/2000/Xtra/5000 according to its intended use.

3.4. Description of any other devices and products which are intended to be used in combination with the device

The medical devices Siluron® 1000/2000/Xtra/5000 are not intended for use in conjunction with other medical devices, medicines, or other medical technologies.

4. Risks and warnings

4.1. Residual risks and undesirable side effects

Side effects / complications associated with vitrectomy together with the application of Siluron® 1000/2000/Xtra/5000 and identified via clinical literature data (resulted from a systematic review of scientific literature) and via complaints reported the Fluoron GmbH in context of Siluron® device application are described in the following:

Side effects and complications	**Expected frequency**	**Time of occurrence (intraoperative, postoperative)**
Anterior eye segment complications (e.g. cataract formation, SO droplets in the AC, secondary capsular opacification, endothelial deposits, dry eyes, corneal oedema/epitheliopathy)	> 1 of 100000 and ≤ 1 of 10000	postoperative
Decrease in visual acuity to vision loss (e.g., choroidal neovas-cularization, branch retinal vein occlusion, visual loss)	> 1 of 100000 and ≤ 1 of 10000	postoperative
Emulsification	> 1 of 10000 and ≤ 1 of 1000	postoperative
Decreased or increased intraocular pressure (e.g., increase in IOP, hypotony)	> 1 of 10000 and ≤ 1 of 1000	postoperative
Retinal re-detachment (e.g., latrogenic retinal tear, re-detachment, peripheral tractional detachment)	> 1 of 100000 and ≤ 1 of 10000	intraoperative (iatrogenic retinal tear/peripheral tractional detachment) or postoperative (redetachment)
Intraocular inflammation (e.g., anterior chamber inflammation, recurrent uveitis, Phthisis bulbi, extensive lymphomatous changes and inflammation, conjunctivitis, blepharitis)	> 1 of 100000 and ≤ 1 of 10000	postoperative
New membrane formation (e.g. ERM, attenuated inner segment/outer segment junction)	> 1 of 100000 and ≤ 1 of 10000	postoperative

Side effects and complications	Expected frequency	Time of occurrence (intraoperative, postoperative)
Migration of silicone oil (e.g., subretinal SO, subconjunctival SO)	> 1 of 10000 and ≤ 1 of 1000	intraoperative (subretinal SO) or postoperative (subconjunctival SO)

Abbreviations: SO – silicone oil, AC – anterior chamber, ERM – epiretinal membrane, IOP – increased intraocular pressure

Further, the following risks were identified via clinical data when performing vitrectomy together with the application of the Siluron® devices:

- Macular pucker (Yanyali et al., 2012 [1])
- Patch not vascularized (Caramoy et al., 2010 [3])
- (Cystoid) macular oedema (Scheerlinck et al., 2016 [8]; Amer, 2019 [10]; Chen et al., 2023 [17])
- Haemorrhage (Scheerlinck et al., 2016 [8]; Stalmans et al., 2015 [9])
- Early SO removal (Farrahi et al., 2014 [2])
- Allergic reactions (Stalmans et al., 2015 [9])

The early removal of the silicone oil was not caused by the silicone oil itself, but by other complications that arose and made secondary surgery necessary. So, this risk is not added to the side effects list of the instructions for use of the Siluron® devices.
Concerning the allergic reactions, a corresponding contraindication is listed in the instructions for use of Siluron® 1000/2000/Xtra/5000. Therefore, this risk of allergic reactions does not need to be included in the list of Siluron® associated side effects.
All other listed risks of the list above (macular pucker, patch not vascularized, (cystoid) macular oedema and haemorrhage) are general complications that may occur when performing vitrectomy. In the clinical data it is not described, that they are directly related to the application of an endotamponade such as Siluron® 1000/2000/Xtra/5000. Therefore, it is not necessary to include these side effects in the Siluron® instructions for use.

In context of the researched clinical literature data of Siluron® 1000/2000/Xtra/5000, the two risks “migration of silicone oil” and “new membrane formation” were identified as new side effects. The list of side effects and complications in the instructions for use of the Siluron® devices was updated accordingly to inform adequately the ophthalmic surgeon about all possible side effects.

All the risks (side effects / complications) described in the table above correspond risks that are in association with vitrectomy together with the application of a silicone oil endotamponade such as Siluron® 1000/2000/Xtra/5000.

With the exception of eyes having a complex baseline situation, the indwelling time for Siluron® 1000/2000/Xtra/5000 should be kept as short as possible and limited to at most 6 months. A short length of indwelling time can reduce potential side effects and complications.

During removal of Siluron® 1000/2000/Xtra/5000 from the eye, attention must be paid to ensure that the silicone oil is completely removed from the eye. Experience has shown that if the silicone oil is removed in the post-operative phase, during which the visual acuity does not continue to increase or drops again, the final result of the surgery can be improved.

Siluron® 1000/2000/Xtra/5000 are not permitted to be used in patients who are hypersensitive to silicone oil or wear a silicone intraocular lens (IOL). In addition, laser coagulation or cryotherapy are not permitted in eyes filled with Siluron® 1000/2000/Xtra/5000.

Interactions with Siluron® 1000/2000/Xtra/5000 may occur if perfluorocarbons are not completely removed (e.g., sticky oil). There are currently no known interactions with other substances.

4.2. Warnings and precautions

- Do not use this device after the expriy date. The expiry date is shown on the devices and on the folding boxes.
- The device is only intended for single use on one patient. Repeated use may lead to microbial contamination, which may cause a severe infection in the patient.
- Use in pregnant women, nursing mothers and children is not recommended.
- Check the integrity of the sterile packaging. Do not use the device if the sterile packaging has been damaged.
- The indwelling time of the device should be kept as short as possible and limited to the recommended duration of use. A short length of indwelling time can reduce potential side effects and complications.
- A leak-free and safe connection of the syringe is ensured by the standardised Luer Lock (according to ISO 80369).
- Glass syringes are potentially fragile due to their material structure. It is recommended that appropriate application systems be used.
- Silicone oil could migrate out of the eye and could form lesions in the conjunctiva or eyelid.
- Avoid wetting the Luer-Lock thread of the syringe with the product Siluron®. The wetting effect can potentially cause the Luer-Lock adapter to detach from the syringe.
- Before Siluron® 1000/2000/Xtra/5000 are permitted to be instilled in the eye, any heavy liquids, e.g., perfluorocarbons of any kind, must be completely removed from the vitreous chamber.
- Excessive instillation of Siluron® 1000/2000/Xtra/5000 in the posterior segment of the eye must be avoided.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

In the current post-market surveillance period (2021 until quarter 3/2025) a field safety corrective action (FSCA) concerning some Siluron® batches was performed by Fluoron GmbH:
In October 2023, cloudiness of the Siluron® device in the patient's eye was observed during the postoperative clinical follow-up phase. This cloudiness presents itself as a temporary restriction of the patient's vision. Droplets as in emulsification could not be observed. Further, the opacity has no effect on the function of the silicone oil as a tamponade of the retina. The patient's temporary visual limitation remains until the silicone oil is explanted and disappears as soon as the oil is removed. Because a third complaint received by Fluoron GmbH with this same failure (postoperative cloudy silicone oil in patient's eye) and simultaneously this reported turbidity leads to user uncertainty, the Fluoron GmbH decided to issue a voluntary recall. The scope of this recall was limited to certain Siluron batches where the same raw material batches were used and were subject to the same manufacturing processes. As root cause of the postoperative cloudy silicone oil in the patient's eye an undesirable admixture (most probably silicic acid) in the silicone oil raw material could be identified, caused by the supplier of the polydimethylsiloxane raw material. To avoid a further case of such an adverse event, the silicone oil raw material specification was expanded by the "turbidity" measurement.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device

Not applicable. The statement of conformity of the device was assessed and endorsed by the Notified Body not on the basis of equivalence.

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking

Not applicable. No clinical investigation was necessary or performed for the product prior to CE marking.

5.3. Summary of clinical data from other sources

Clinical data obtained from scientific literature:

To gather the relevant publicly available information on the performance and safety of the Siluron® 1000/2000/Xtra/5000 devices, a systematic literature search was performed in context of the clinical evaluation of Siluron®. The search was conducted in online databases using defined keywords and operating of a search strategy. PubMed, NCBI and Scite_interfaces were searched as well as search on a clinical trial portal was performed. The searches in clinical trial registries retrieved no relevant results.

The medical devices Siluron® 1000/2000/Xtra/5000 have been marketed all over the world for several years. Accordingly, an acceptable amount of publications on the clinical use of these medical devices are publicly available.
Twenty publications on their clinical use were identified (in PubMed, Embase, and Google Scholar) and were considered relevant and included for appraisal. All the publications stated Siluron® as product tradename and most of them stated Fluoron GmbH or Geuder AG as manufacturer of the silicone oils.

With regard to performance, good tamponade effect, easy removal from the eye (procedural success), re-attachment rate in cases of retinal detachment and macular hole closure rate for the treatment of macular holes (anatomic success) and improvement of visual acuity (functional success) have been identified as the parameters the concerned devices have to be compared to alternative treatments.

Procedural success
Tamponade effect and ease removal from the eye
In context of the performed usability evaluation the average quality of the tamponade effect was rated 1.6 points on a scale from 1 (very good) to 5 (very bad) across all Siluron devices. In addition, the ease of removal of the concerned devices was rated 1.8 points. Overall, the average values of all reported results were 2.1 points or better, and thus met the predefined acceptance level of at least 3 points for the concerned devices and the two clinical benefits or procedural success could be demonstrated.

The ease of application and removal was described for Siluron 2000 and 5000 in a publication by Stalmans et al. 2015 [9]. To evaluate the ease of injection and extraction the authors reported the amount of time required to inject/extract the oils. They found that Siluron 2000 provided superior handling compared with Siluron 5000, because both injection and removal of Siluron 2000 were significantly faster, and similar to that of 1,000 cSt silicone oil.
The reattachment rate in cases of retinal detachment or closure rate of macular holes when using Siluron® devices as long-term endotamponades are described in the literature. A reattachement rate of the retina of 91.6% in more than 300 patients (Yanyali et al., 2012 [1], Gerding and Hersener 2013 [5], Hussain et al., 2017 [7], Amer 2019 [10]) and a macular hole closure rate of 100% (Stalmans et al., 2015 [9]) reflects a successful tamponade of the Siluron® devices.

So, it can be concluded that the tamponade effects and easy removal from the eye meet the predefined acceptance level, so that procedural success could be demonstrated for the concerned devices.

Anatomic success
Retinal detachment (reattachment rate)
The anatomic success rates obtained with the concerned devices (Siluron® 1000/2000/Xtra/5000) are described in four studies which altogether included 309 patients. An average reattachement rate of the retina of 91.6% in more than 300 patients (Yanyali et al., 2012 [1], Gerding and Hersener 2013 [5], Hussain et al., 2017 [7], Amer 2019 [10]) could be determined based on the clinical data. Further, the results obtained with Siluron® devices show a better reattachment rate of the retina than the predefined acceptance value (87.57%) from state-of-the-art (SOTA) data.
Macular hole (closure rate)
The concerned devices show better anatomical success rates as the results reported in meta-analyses and review articles as well as those observed with similar devices. Thus, Stalmans et al., 2015 [9] reported closure rates of 94.3 % on the day after vitrectomy and 100 % before oil removal for 72 patients treated with both standard and blend silicone oils.

In summary, depending on the severity of the pre-operative status, very good results were achieved with the devices under evaluation for treatment of both retinal detachment and macula holes. Thus, anatomic success – which was defined as success rates equal to or better with benchmark devices from SOTA data – could be demonstrated.

Functional success (improvement of visual acuity)
Retinal detachment
Altogether, ten studies including more than 1,900 patients reported clinical data on the visual acuity after treatment with Siluron® devices. In most of the studies, stabilisation or improvement of the visual acuity was observed. Postoperative visual acuity was between 0.083 logMAR and 1,79 logMAR in all studies. In the publication reporting the worst visual outcome (1,79 logMAR), the authors compared their results to 2 other, larger series and found similar success rates, which they described as satisfactory given the cohort of patients treated (Hussain et al., 2017 [7]). Two of the identified studies compared the outcomes of visual acuity after silicone oil tamponade to those obtained with gas tamponade. One of these studies found no statistically significant difference in mean postoperative visual acuity for silicone oil tamponade compared to gas tamponade (Scheerlinck et al., 2018 [12]). In the other study, better results were obtained with gas tamponade, which could possibly be explained by the severe conditions, such as giant tears, multiple

defects, PVR and failed previous surgery, that were treated with silicone oil tamponade (Scheerlinck et al., 2016 [8]).

Macular hole
For the 72 patients with macular holes treated with Siluron® 2000 and Siluron® 5000 Stalmans et al., 2015 [9] reported an increase in visual acuity from baseline to 6 weeks after vitrectomy of 10 and 15 letters, respectively, and 6 weeks after oil removal of 14 and 10 letters, respectively (improvement of 5 letters corresponds to an improvement of 0.1 on the logMAR scale/1 line). The observed increase in visual acuity of 2-3 lines is comparable to the results reported in the description of the state of the art (section 3.2.2.2 and 3.2.3).
The clinical benefit and outcome parameter for the functional success of Siluron® 1000/2000/Xtra/5000 was defined as an improvement in visual acuity equal to or better than 0.77 logMAR. The clinical data show an average improvement in visual acuity of 0.47 logMAR for Siluron® 1000/5000 and 0.21 logMar for Siluron® 2000/Xtra. The average improvement of visual acuity from the clinical data deviates from the predefined acceptance value of 0.3 logMAR or 0.56 logMAR. However, it should be noted that the clinical benefit and outcome parameter for the devices under evaluation could only be determined on the basis of seven publications. In the remaining three publications, no logMAR values were given, only an improvement was reported or an average value was given. As overall the visual acuity of patients treated with Siluron has improved, the efficacy of the products in improving visual acuity has been proven.

Overall, the procedural, anatomical and functional success rates are comparable with values reported for comparable long-term tamponades and benchmark devices in the state of the art. Thus, the above described publications on Siluron® 1000/2000/Xtra/5000 show that the silicone oils can be used successfully as long-term tamponade for the treatment of retinal detachment and as tamponades in macular hole surgery. Performance of the devices is adequately supported with clinical data for the claimed indications and patient populations and can therefore be regarded as proven.

Silicone oil in children and adolescents
There are numerous reports concerning the use of silicone oil in adults, but the performance and benefits of these tamponades in the paediatric population have barely been investigated.
Two publications describe the use of the silicone oil tamponades Siluron® 1000/5000 in children / adolescents.
A 13-year retrospective chart review of 5,097 consecutive patients undergoing pars plana vitrectomy, reported the use of Siluron® 1000/5000 as endotamponade in more than 1,500 patients (Teke et al., 2013 [14]). The study included 106 children (age not specified) who underwent vitreoretinal surgery due to retinal detachment. In all these children, Siluron® (1000 or 5000, not detailed) was used instead of gas as vitreous supplement due to the difficulty in achieving postoperative positioning and the advantage of media clarity.
Furthermore, Leow and Bastion 2013 [4] reported the case of an adolescent patient with unilateral RRD, the patient had several complications including redetachment, which was treated with laser, however, a second surgery was required for silicone oil removal from the first procedure, retinectomy and insertion of Siluron® 5000. Unfortunately, the patient was lost to follow up. Therefore, the outcome of the procedure cannot be described.
It is concluded that silicone oils, based on clinical data on Siluron® 1000/5000 and other silicone oils, seem to be safe endotamponades also in children. However, because this is supported by only limited amount of data, the use of Siluron® 1000/2000/Xtra/5000 in children is not recommended.

Use of Siluron® in pregnant women and nursing mothers
No studies have been identified that described the use of Siluron® 1000/2000/Xtra/5000 in pregnant women or nursing mothers. Moreover, this patient population was explicitly excluded from several studies (e.g. Hussain et al., 2017 [7], Abdullatif et al., 2018 [18]). As no clinical experience is available, Siluron® 1000/2000/Xtra/5000 is not recommended in pregnant women and nursing mothers.

With regard to safety, the safety relevant data such as device material/device properties (e.g., chemically and physiologically inert, non-toxic, biocompatible, high-pure), non-clinical safety data, the usability evaluation data and the post-market surveillance data did not identify any special safety concern or risk in context of the use of Siluron® 1000/2000/Xtra/5000.
Further, the following risks (side effects and complications) associated with vitrectomy together with the application of Siluron® 1000/2000/Xtra/5000 were identified via clinical literature data and via complaints reported the Fluoron GmbH in context of Siluron® device application:
anterior eye segment complications, decrease in visual acuity to vision loss, emulsification, decreased or increased intraocular pressure, retinal re-detachment, intraocular inflammations, new membrane formation and migration of silicone oil.
The two risks “migration of silicone oil” and “new membrane formation” were identified as new side effects within the scope of the researched clinical literature data of Siluron® 1000/2000/Xtra/5000. The list of side effects and complications in the instructions for use of the Siluron® devices was updated accordingly.

All these side effects / complications described in context of application of a Siluron® device are well within the normal range of patients suffering from complicated retinal detachment with or without proliferative vitreoretinopathy as well as macular holes as compared to the similar devices.
Furthermore, all these side effects / complications were evaluated within the Siluron® risk assessment, and corresponding risk control measures were implemented. The risk evaluation showed that the benefit still outweighs the possible risks in context of a Siluron® 1000/2000/Xtra/5000 application.

Clinical safety data on Siluron® 1000/2000/Xtra/5000

The majority of the identified literature data on Siluron® 1000/2000/Xtra/5000 do not mention complications related to the application of the silicone oils. Most of the identified publications describe complications in general for the procedures performed and the mentioned complications are not attributed to silicone oil tamponade only, since different kinds of tamponades were used.
Complications that occurred in clinical studies are described in the following.

Siluron® 1000/5000
In a prospective, comparative case-control study on phakic or pseudophakic patients conducted by Farrahi et al., 2014 [2] the corneal endothelium in silicone oil filled vitrectomised eyes was evaluated. From a total of 156 eyes, 46 eyes were excluded, in the course of study, due to need to silicone oil removal in 26 eyes, anterior chamber inflammation in 4 eyes, progression of cataract leading to phacoemulsification surgery in 10 eyes and rise of intraocular pressure in 6 eyes.
Yanyali et al., 2012 [1] analysed retrospectively 49 patients undergoing a 23-gauge vitreoretinal surgery for Rhegmatogenous retinal detachment (RRD). The following post-operative complications were reported Cataract formation or progression 38.5%, redetachment 4.1%, macular pucker 6.1%, silicone oil droplets in anterior chamber 10.2%, glaucoma controlled by topical medication 4.1% and transient hypotony 2.0%. These complications are not attributed to silicone oil tamponade only, since different kind of tamponades were used. Subconjunctival leak of silicone oil was not seen in any cases. Leakage, extension, dehiscence and haemorrhage, or vitreous or retinal incarceration at the external side of the sclerotomies was not observed in any eye.
The retrospective chart review including 1,571 patients (of those 106 children) reported the use of Siluron®1000/5000 as endotamponade) [14]. Three intraoperative cases of silicone oil fledding the subretinal space, 132 cases of subconjunctival silicone oil occurring at day 1 post-operatively, and 16 cases of subconjunctival silicone oil occurring post-operatively after 6 months). It was however, not stated whether these complications were observed in children or adult patients). It can be concluded that silicone oils, based on clinical data on Siluron® 1000/5000 and other Siluron oils, can be considered as a safe endotamponade also in children. However, currently the data are not considered sufficient to recommend the use of Siluron® 1000//2000/Xtra/5000 in children.
In a series of 157 eyes treated with pars plana vitrectomy for RRD described by Gerding and Hersener 2013 [5] patients received either gas or silicone end tamponades (4.5% treated with Siluron® 5000). 73 of primarily 89 phakic eyes (82.0%) received cataract surgery during the follow-up period, 1 eye (1.1 %) at the occasion of the first intervention, 5 eyes (5.6%) at the time of silicone removal and the remaining 67 eyes (75.2 %) later (average: 283 ± 260 days, range: 52- 1385 days). Secondary retinal detachment due to proliferative vitreoretinopathy became necessary in 8 eyes (5.1 %, 7 cases with previous gas end tamponade, 1 case with silicone endotamponade).
Caramoy et al., 2010 [3] evaluated the long-term outcome of autologous graft of retinal pigment epithelium in patients with age related macular degeneration. As post-operative late complications, classic or occult choroidal neovascularisation (CNV) appeared in three eyes (30%) at the border of the graft. At the last follow-up examination, the CNVs had spontaneously become scarred without any additional treatment. Epiretinal membrane formation with cystoid retinal oedema was confirmed by optical coherence tomography (OCT) in three eyes (30%) at the last follow-up examination; in these cases, no internal limiting membrane peeling had been performed. Other post-operative complications included retinal detachment due to proliferative vitreoretinopathy not involving the macula in three eyes (30%), branch retinal vein occlusion and iritis in one eye, and transient ocular hypertension in two eyes.
Ni et al., 2019 [11] performed a retrospective case study to identify the reason for earlier silicone oil emulsification in their hospital in China. Silicone oil removal is usually performed 4-6 months after injection. They noticed that the occurrence of silicone oil emulsification became earlier and more frequent than before and retrospectively looked at an unknown number of eyes of 182 patients. The authors identified Siluron® 2000 as being responsible for the higher number of earlier emulsifications without describing concrete details. They warrant further studies to find out the underlying causes.
In a retrospective observational study of Jmor et al., 2019 [15] the disease burden of raised intraocular pressure from silicone oil pars-plana vitrectomy was reviewed. The occurrence of raised intraocular pressure and requirement for glaucoma medication and surgery post silicone oil pars-plana vitrectomy were assessed. Nearly one third of patients remained in need of monitoring and treatment for raised intraocular pressure, 5 years after silicone oil pars-plana vitrectomy. Of these a third required ≥ 3 medications to maintain intraocular pressure, and 10 % needed glaucoma surgery.
Chen et al., 2023 [17] performed a retrospective study to compare the effects of silicone oil tamponade on the choroidal vascular index (CVI) and choroidal thickness (CT) patients with unilateral Rhegmatogenous retinal detachment (RRD) with operated eyes and fellow healthy eyes. In total 36 patients were included

and received silicone oil tamponade for unilateral complicated RRD. Four patients had macular edema which disappeared after the removal of silicone oil.

Siluron® 2000/Xtra

The incidence, risk factors and clinical characteristics of unexplained visual loss after silicone oil application was investigated in a cohort study conducted by Scheerlinck et al., 2016 [8]. Of the patients treated by silicone oil tamponade, 20 (54%) experienced visual loss, which could be explained in 9 eyes. Reasons for a decreased best-corrected visual acuity (BCVA) were cataract formation (2.7%), secondary capsular opacification (13.5%), cystoid macular oedema (2.7%), and vitreous haemorrhage (2.7%). Post-operative BCVA of 1 eye (2.7%) improved within 6 months. Visual loss remained unexplained and without improvement in 11 eyes (29.7%) and occurred during silicone oil tamponade in 8 eyes (21.6%) and after silicone oil removal in 3 eyes (8.1%). No structural abnormalities were present on optical coherence tomography (OCT), such as disruption of the inner segment/outer segment junction or retinal pigment epithelium.

Scheerlinck et al., 2018 [12] investigated whether intraocular silicone oil tamponade is associated with functional changes in patients with both macula-on and macula off Rhegmatogenous retinal detachments (RRDs). In total, 40 eyes were included. There were 10 eyes in each of the following groups: macula-on RRD and gas, macula-on RRD and silicone oil, macula-off RRD and gas, and macula-off RRD and silicone oil. Median retinal sensitivity on microperimetry was decreased following silicone oil tamponade compared to gas tamponade for both macula-on and macula-off RRD ($p < 0.037$). Foveal sensitivity was decreased in eyes after silicone oil tamponade compared to gas tamponade. These effects were observed in patients with macula-on as well as macula-off RRD. Although further investigation is warranted to validate the results and to study underlying mechanisms, retinal surgeons need to be aware of these findings after the use of silicone oil tamponade.

Hussain et al., 2017 [7] reported one case of emulsification (3.5% of patients), oil entered the anterior chamber in a single patient (3.5%). Two patients developed phthisis bulbi (7%) and a further 2 (7%) developed epiretinal membrane. A patient with lymphoma (phakic) had a subsequent enucleation for extensive lymphomatous changes and inflammation. Cataract developed in 3 of 6 patients (50%) requiring surgery. There was a single case of unexplained visual loss following oil removal.

Amer, 2019 [10] reported the results from a prospective, interventional and non-randomized study on 75 eyes (75 patients) with RRD. 71 of the 75 eyes, had a successful vitrectomy with reattached retina under silicone oil tamponade and 4 eyes were excluded. Postoperative OCT changes included attenuated inner segment/outer segment junction in 16 (22.54%) eyes, macular oedema in 15 (21.13%) eyes, epiretinal membrane in 13 (18.31%) eyes.

In a randomised controlled study conducted by Stalmans et al., 2015 [9] the safety and efficacy of Siluron® 2000 in the treatment of macular hole was evaluated and compared to Siluron® 5000. The occurrence of serious adverse events per patient was 0% in patients treated with Siluron® 2000 compared with 5.6% (N = 2) in patients treated with Siluron® 5000 (P = 0.49). After oil removal, the occurrence of serious adverse events was 2.8% (N = 1) in patients treated with Siluron® 2000 compared with 0% in patients treated with Siluron® 5000 (P = 1.00). From vitrectomy up to oil removal, the occurrence of ophthalmic adverse events (AEs) was 44% (N = 16) in patients treated with Siluron® 2000 compared with 42% (N = 15) in patients treated with Siluron® 5000 (P = 1.00). After oil removal the occurrence of ophthalmic AEs was 25% (N = 9) in patients treated with Siluron® 2000 compared with 28% (N = 10) in patients treated with Siluron® 5000 (P = 1.00). Before oil removal, the occurrence of AEs was 50% (N = 18) in patients treated with Siluron® 2000 compared with 56% (N = 20) in patients treated with Siluron® 5000 (P = 0.81). No late reopenings after silicone oil removal were observed. Adverse events included elevated intraocular pressure, endothelial deposits, oil droplets in anterior chamber, retinal haemorrhage, branch retinal vein occlusion, conjunctivitis, allergic reaction, dry eye, blepharitis, and corneal oedema/epitheliopathy. However, it was not specified which events occurred most frequently in each group.

Veckeneer et al., 2017 [6] conducted translocations of autologous retinal pigment epithelium-choroid grafts for complicated neovascular age related macular degeneration. Thereby complications such as blood at the harvesting site in all patients, haemorrhages around the translocated graft (22.2% of patients) and cystoid macular oedema (16.7% of patients) occurred. In one patient (5.5%), although no signs of proliferative vitreoretinopathy (PVR) were present, the inferior retinotomy edge appeared only loosely adherent during the attempted oil removal 4 weeks after the graft surgery. Additional laser was applied, and oil was reinjected for another 8 weeks, after which the retina was completely attached and the oil could be removed. None of the patients developed PVR-related pathology.

Soliman et al., 2018 [13] investigated cataractous changes due to silicone oil as the most common complication of silicone oil injection after vitrectomy. They performed a prospective, controlled, non-randomized, interventional study with 20 anterior lens capsular specimens that were excised during combined clear lens extraction and silicone oil removal from previously vitrectomised highly myopic patients with silicone oil tamponade for previous retinal detachment surgeries. The specimens were examined via light microscopy and electron microscopy and compared with 20 anterior capsule specimens removed during clear lens extraction of non-vitrectomised highly myopic eyes. silicone oil may play a role in the development of apoptotic and histopathological changes in clear lens epithelial cells. Clarity of the lens at the time of silicone oil removal does not indicate an absence of cataractous changes. They found justification of combined clear lens extraction and silicone oil removal or combined phacovitrectomy when silicone oil injection is planned, but further long-term studies with larger patient groups are required. The

findings may reduce the burden associated with undergoing multiple surgeries after retinal detachment surgery.
Ng et al., 2023 [16] performed a retrospective study to assess the safety and effectiveness of the exclusive use of 27-gauge instruments for all vitreoretinal diseases requiring vitrectomy. Primary macular hole closure was achieved in 143 of 145 (99 %) cases. Of the 148 retinal detachment cases performed, 138 (93 %) required a single vitrectomy. Complications recorded include transient hypotony in 39 eyes.

Included Literature in which the devices in question were used

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Clinical data obtained from Post Market Surveillance:

The following post-market surveillance activities were gathered and analysed: information concerning serious incidents, information from field safety corrective actions (FSCAs), data of complaints (involving non-serious incidents and undesirable side-effects), information on reporting trends, specialist literature data (state-of-the-art data and clinical data), technical literature data, data of regulatory and vigilance databases, data of similar devices, data of the post-market clinical follow-up (PMCF) activity and data of preventive and/or corrective actions (CAPA).

Information from serious incidents / field safety corrective actions

In October 2023 the Fluoron GmbH performed a field safety corrective action: during the postoperative clinical follow-up phase cloudiness of the Siluron® device in the patient's eye was observed.
For more details see section 4.3.

Complaints

During the complaint data collection period (from 2021 until 2025-07-18) the annual Siluron® complaint rate was very low (≤ 0.01%), respectively. Further, in total 16 complaints with association of Siluron® application were reported to Fluoron GmbH. One of these 16 complaints was withdrawn from the customer, because the alleged accumulation of proliferative vitreoretinopathy when using Siluron® had other causes than the initially suspected problem with the Siluron® tamponade itself.
"Postoperative turbidity of silicone oil" is the most common complaint (5 cases, percentage of 31.25%). Following the third complaint received by Fluoron GmbH with the same defect (clouding of the silicone oil in the patient's eye during the clinical follow-up phase), Fluoron initiated a voluntary recall of the affected Siluron® batches (for more details see section 4.3). The two other complaint reports each describes a clouding of a silicone oil of the Siluron® batch Sil1 10S 170523, whose recall from the market has already startet. So, no further measures are necessary here.
The complaint type "water stains on sterile pouch (paper side)" occurred three times during the current data collection period from 2021 until 2025-07-18. Water stains may occasionally occur during the drying process within the sterilization process in the autoclaves. Corresponding corrective measures were implemented (e.g., maintenance of the autoclave, 100 % visual check of the sterile pouch integrity after the autoclaving process) to reduce this risk as far as possible. All the products complained about regarding the water stains were not used on the patients, i.e. did not result in any risk to patients or third parties.
All other types of complaints occurred only once or twice in the period between 2021 and 2025-07-18.
All complaints / risks reported to Fluoron GmbH in context of Siluron® device application during time period from 2021 until 2025-07-18 have already been evaluated within the risk analysis of the Siluron® devices.

Trend reporting

The feedback from the market did not result in any changes in the assessment of severity of harm.
Further, the feedback from the market resulted in changes of the probability of occurrence of three hazard situations (complaints). Resulting from these adjustments of the probabilities of occurrence, all these three risks remain within the acceptable risk range.
Further, the assessment of all Siluron® risks showed that the overall risk has a positive benefit-risk ratio, i.e. the medical benefit of the medical devices Siluron® 1000/2000/Xtra/5000 still outweighs the possible risks of using these silicone oil tamponades. So, a reportable trend according to the Article 88 of the MDR 2017/745 does not exist.

Post-market clinical follow-up (PMCF) activity / Specialist literature data

As a PMCF activity, a systematic literature search review was performed. This literature review resulted in publications describing state-of-the-art and clinical data on silicone oil such as Siluron® 1000/2000/Xtra/5000 or similar devices during use on treatment of severe cases of retinal detachment or macular holes.
The PMCF activity showed the following results:

- the state-of-the-art and clinical literature data have an appropriate quality to confirm relatively good the state-of-the-art of the treatment and the actual clinical performance and safety of the medical devices Siluron® 1000/2000/Xtra/5000, respectively. So, the identified state-of-the-art data and appraisal of the clinical data of Siluron® 1000/2000/Xtra/5000 confirm the safety and clinical performance of these silicone oil tamponades.
- the searched literature data identified no kind of any new risk of a clinical perspective or any previously unknown side effect. Furthermore, no previously unknown contraindication was identified. Thus, the acceptance of the benefit-risk ratio of the silicone oil tamponades Siluron® 1000/2000/Xtra/5000 is continued guaranteed.

- in the new identified state-of-the-art and clinical data no possible systematic misues or off-label use of Siluron® 1000/2000/Xtra/5000 were determined.

Technical literature data
The review of the technical literature data – relevant applicable standards / laws / regulations / guidelines – showed, that the Siluron® devices are manufactured in conformity with current standards/guidelines and legislation.

Data of regulatory and vigilance databases
Searches in regulatory/vigilance databases of different countries:
The MAUDE (USA) database search resulted in 18 relevant hits describing complications, which have already been known in association with a silicone oil tamponade application such as Siluron® and are all listed in the Siluron®'s instructions for use under item "side effects and complications".
The search of the Health Canada database resulted in one relevant hit describing a labelling error, which corresponds to a known risk of the Siluron® devices.
The search of the German BfArM database resulted in one relevant hit describing the voluntary recall performed on Siluron® batches of Fluoron GmbH in October 2023. Here, corresponding measure was implemented (raw material specification was extended by the turbidity measurement) to reduce this risk of postoperative turbidity of the silicone oil in the patient's eye as far as possible.

Detailed search in BfArM's database (database of the German Federal Institute for Drugs and Medical Devices):
The detailed BfArM's database search revealed that no new risks/hazards were identified. So, the risk assessment of the Siluron® device group does not need to be updated. Furthermore, the evaluation of the identified 87 relevant incidents showed that appropriate control measures for the silicone oil tamponades Siluron® 1000/2000/Xtra/5000 from Fluoron GmbH have been implemented for all the product problems described in these 87 relevant incidents. That means the chosen control measures are effective.

Data of similar medical devices
The publicly available information gathered of medical devices, which are presumed to be similar to the Siluron® devices, show the following result:
All the clinical / biological / technical characteristics of the Siluron® devices and all these medical devices by other manufacturers are similar or equivalent. That means, all these other medical devices are similar devices to Siluron® concerning the clinical / biological / technical characteristics, respectively.

Preventive and/or corrective actions (CAPA)
All CAPAs of internal non-conformities and such CAPAs resulting from audits (external, internal) were assessed for any direct impact on product safety, performance or quality. The result of this CAPA evaluation for time period from 2019 until June 2025 showed that no CAPAs were detected, which had a direct impact on product safety, performance or quality of the medical devices Siluron® 1000 / 2000 / Xtra / 5000.

Overall summary clinical data obtained from Post Market Surveillance
From the Siluron® post-market surveillance activities no new risk was identified.
No new benefits of the medical devices Siluron® 1000/2000/Xtra/5000 were identified during the post-market surveillance of these devices.
Furthermore, the post-market surveillance data analyses of the Siluron® devices do not result in any changes in the assessment of severity of harm of an already known risk.
Simultaneously, the post-market surveillance data analyses of the Siluron® devices result in changes in the assessment of probability of occurrence of three risks. As a result of these adjustments of the probabilities of occurrence, all these three risks remain within the acceptable risk range.

So, the following is valid for the Siluron® devices:
Based on the analyses of the collected post-market surveillance data, it is concluded that the benefit-risk profile of the medical devices Siluron® 1000 / 2000 / Xtra / 5000 has not been adversely impacted. That means, the benefit-risk ratio of the Siluron® devices remains unchanged and thus is still positive.

Clinical data from medical device registries:
Not applicable. Registries are not performed with the medical devices under assessment.

5.4. An overall summary of the clinical performance and safety

Performance:
With regard to performance, the following parameters are considered as relevant for the Siluron® devices: good tamponade effect (procedural success), easy removal from the eye (procedural success), re-attachment rate in cases of retinal detachment and macular hole closure rate for the treatment of macular holes (anatomic success) and improvement of visual acuity (functional success).
Overall, the procedural, anatomical and functional success rates are comparable with values reported for comparable long-term tamponades and benchmark devices in the state of the art. That means Siluron® 1000/2000/Xtra/5000 can be used successfully as long-term tamponade for the treatment of retinal detachment and as tamponades in macular hole surgery. Performance of these silicone oil devices is adequately supported with clinical data for the claimed indications and patient populations and can therefore be regarded as proven.

Safety:
With regard to safety, the safety relevant data such as device material/device properties (e.g., chemically and physiologically inert, non-toxic, biocompatible, high-pure), non-clinical safety data, the usability evaluation data and the post-market surveillance data did not identify any special safety concern or risk in context of the use of Siluron® 1000/2000/Xtra/5000.
Further, the following risks (side effects and complications) associated with vitrectomy together with the application of Siluron® 1000/2000/Xtra/5000 were identified via clinical literature data and via complaints reported the Fluoron GmbH in context of Siluron® device application:
anterior eye segment complications, decrease in visual acuity to vision loss, emulsification, decreased or increased intraocular pressure, retinal re-detachment, intraocular inflammations, new membrane formation and migration of silicone oil.
The two risks “migration of silicone oil” and “new membrane formation” were identified as new side effects within the scope of the researched clinical literature data of Siluron® 1000/2000/Xtra/5000. The list of side effects and complications in the instructions for use of the Siluron® devices was updated accordingly.

All these side effects / complications described in context of application of a Siluron® device are well within the normal range of patients suffering from complicated retinal detachment with or without proliferative vitreoretinopathy as well as macular holes as compared to the similar devices.
Furthermore, all these side effects / complications were evaluated within the Siluron® risk assessment, and corresponding risk control measures were implemented. The risk evaluation showed that the benefit still outweighs the possible risks in context of a Siluron® 1000/2000/Xtra/5000 application.

Conclusion
The clinical performance and the safety of the silicone oil tamponades Siluron® 1000/2000/Xtra/5000 have been verified based on clinical literature data, the usability evaluation data and the post-market surveillance data.
So, if the Siluron® devices are applied according to the intended use as specified in the instructions for use, there is no concern on the acceptability of the well-known undesirable side effects, and the benefit outweighs the possible risks in context of a Siluron® 1000/2000/Xtra/5000 application.

5.5. Ongoing or planned post-market clinical follow-up

PMCF activity: Systematic literature review

A systematic literature search was performed to gather and evaluate state-of-the-art data and clinical data on the medical devices Siluron® 1000 / 2000 / Xtra / 5000 for confirmation the clinical evidence (safety and clinical performance) of these medical devices and to achieve all other aims of the PMCF activity (see table below).

Description of activity	Aim of the activity	Rationale and known limitations of the activity	Timelines of the activity
Systematic literature search review according to the requirements of MEDDEV 2.7/1, Rev.4 and the MDR 2017/745.	○ **Continuous evaluation of the evidence (safety and performance)**	**Rationale of the PMCF activity:** **The silicone oil tamponades Siluron® 1000 / 2000 / Xtra / 5000**	**Literature review will be finalized until end of Q3/2025.**

Description of activity	Aim of the activity	Rationale and known limitations of the activity	Timelines of the activity
	from Siluron® 1000 / 2000 / Xtra/ 5000 and defined similar devices. ○ **identifying previously unknown side-effects and monitoring the identified side-effects and contra-indications;** ○ **identifying and analysing emergent risks on the basis of factual evidence;** ○ **ensuring the continued acceptability of the benefit-risk ratio;** ○ **identifying possible systematic misuse or off-label use of the devices (with a view to verifying that the intended purpose is correct).**	**have been on the market since more than 10 years, namely since 2002 (Siluron® 1000 and Siluron® 5000) / 2008 (Siluron® 2000) / 2013 (Siluron® Xtra). That means all residual risks relating to the use of Siluron® 1000 / 2000 / Xtra / 5000 are known. Furthermore, an acceptable amount of publications on the clinical use of the medical devices Siluron® 1000 / 2000 / Xtra / 5000 are publicly available. There is sufficient clinical evidence of the Siluron® 1000 / 2000 / Xtra / 5000 products for treatment of severe cases of retinal detachment and treatment of macular holes. Thus, the benefit-risk pro-file of Siluron® 1000 / 2000 / Xtra / 5000 is well characterized and positive. For this reason, it is sufficient to conduct a systematic literature search review to achieve all the aims of a PMCF activity.** **<u>Limitations of the PMCF activity</u>:** ○ **number and kind of databases searched,** ○ **search queries (search terms and restrictions),** ○ **time period of the performed searches.**	

Unanswered questions relating to the use of the devices:
There are no unanswered questions relating to the use of the Siluron® devices; therefore, further investigations are not applicable.

Detection of emerging risks, complications or unexpected device failures:
In the context of the performed PMCF activity - systematic literature search review – no new risk or any new side effect of the Siluron® devices was identified. So, the medical benefit of the device group Siluron® still outweighs the possible risks of using the Siluron® devices, respectively.

6. Possible diagnostic or therapeutic alternatives

The vitreous body is a gelatinous substance mainly composed of water, with structural components of hyaluronic acid and different types of collagen. It fills the vitreous chamber, the space between the lens and the retina. Due to its viscoelastic properties it absorbs the stress and strain of the bulb during the movement. Besides its role as a filling substance, the vitreous also has an active role in ocular physiology. The presence of active cells and molecules allows control over inflammation, proliferation, and neovascularisation. In addition, it acts as a barrier to bacterial infection and as repository for oxygen and nutrients. Since 1960, researchers have tried to find adequate substitutes to replace the physical and biological functions of the vitreous. Different currently available tamponade agents able to fulfil this function are summarised below.

Gas

Small volumes of undiluted gas are typically used for pneumatic retinopexy, larger volumes for pars plana vitrectomy. Sulphur hexafluoride (SF_6), perfluoroethane (C_2F_6) and perfluoropropane (C_3F_8) are the most commonly used gases. They present a high surface tension and a specific gravity lower than water to maintain the tamponade effect. SF_6 exerts an effect for 1 to 2 weeks, whereas C_3F_8 persists for 6 to 8 weeks. Due to their longer permanence compared to air they represent the standard gases used in pneumatic retinopexy and vitreoretinal surgery. As with air, the buoyancy (upward force) of the gas bubble keeps the retina against the pigment epithelium. Due to their very low specific gravities (0.001 g/ml) they have a much greater buoyancy than silicone oils. Because the effect is greatest at the upper side of the bubble, this results in a good tamponade of the upper retina, while the patient is in an upright position, but a less effective support of the lower retina. Fundus evaluation is problematic until gas reabsorption due to the lower refractive index of the gases, which causes almost complete reflection of light. Patients with intraocular gases should be advised against air travel or traveling to high altitude, and they should avoid diving. The advantage of these gases is that they are slowly removed via the blood and replaced with aqueous humour. This makes it unnecessary to perform another surgical procedure to remove the gas from the eye, as in the case of the silicone oils. These gases are used in less complicated cases due to their shorter indwelling times in the eye (with approx. 30 days, C_3F_8 has the longest effective period among the three gases listed above). Due to the fact that gases expand rapidly with any drop in air pressure, travel by plane and stay at higher elevations are contraindicated in cases where the vitreous cavity has been instilled with gas.

Silicone oils

Silicone oils have been used to act as internal tamponades in vitreoretinal surgery procedures for more than 40 years. Their use as intra-operative tool to stabilise the retina can be adopted in difficult cases of retinal detachment such as those complicated with proliferative vitreoretinopathy, giant retinal tears, and penetrating ocular trauma. With the introduction of pars plana vitrectomy, silicone oils became also the standard medium for post-operative long-term tamponade in the vitreous cavity following re-attachment of the retina. Silicone oil agents are used to ensure retinal adherence following retinopexy for the time necessary to generate a permanent seal, to control intraocular haemorrhages, and to maintain intraocular pressure. As with gas, the good tamponade effect of silicone oils is restricted to the upper retina when the patients head is in an upright position. Lately developed silicone oil blends contain 5-10% long chain high molecular weight silicone oil (2.5 Mio mPas, 423 kDa) and 90-95% 1000 mPas silicone oil. By adding 5-10% high molecular weight silicone oil the shear viscosity increases, providing the oils with a high resistance to emulsification and maintaining good injectability.

7. Suggested profile and training for users

Siluron® 1000/2000/Xtra/5000 devices are prepared and used exclusively by qualified personnel for intraocular surgery. They have completed a medical degree and the corresponding specialist training. The users have experience with comparable products, because silicone oil tamponades belong to the usual aids in the field of ophthalmic surgery.

Patients themselves have no opportunity to apply and/or influence the medical device.

8. Reference to any harmonised standards and CS applied

Directives and laws:

COUNCIL DIRECTIVE 93/42/EEC of June 1993 concerning medical devices

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (last consolidated version).

COMMISSION RECOMMENDATION of 24 September 2013 on the audits and assessments performed by notified bodies in the field of medical devices ((EU) 2013/473)

Implementing rules for Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use for medical devices ((EU) 2021/2226)

Commission Implementing Regulation (EU) 2021/2078 of 26 November 2021 laying down detailed rules for the implementation of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European database for medical devices (Eudamed)

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions for certain medical devices and in vitro diagnostic medical devices.

Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices supporting Regulation (EU) 2017/745 of the European Parliament and of the Council (latest consolidated version)

Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the phased introduction of Eudamed, the obligation to provide information in the event of interruption or discontinuation of supply, and the transitional provisions for certain in vitro diagnostic medical devices

Regulation governing the dispensing of Medical Devices (Medical Devices Dispensing Regulation – “MPAV”)

Act on the Implementation of Union Regulations Concerning Medical Devices (Medical Devices Implementation Act – “MPDG”)

Medical Devices User Notification and Information Ordinance

Medical Device Adaptation Act EU

Regulation on the installation, operation and use of medical devices (“MPBetreibV”)

Therapeutic Products Advertising Act

Guidances:

MEDDEV 2.7/1, Rev. 4: 2016-06: Clinical evaluation: A guide for manufacturers and notified bodies

MEDDEV 2.12-1, Rev.8: 2013-01: Guidelines on a medical devices vigilance system

GHTF (Study Group 3): 2004-02: Quality Management Systems – Process Validation Guidance

European Pharmacopeia (Ph. Eur.), edition 11: 2023-01
MDCG 2019-0, Rev.1: 2022-03: Summary of safety and clinical performance

MDCG 2019-8 v2: 2020-03: Guidance document implant card on the application of Article 18 Regulation (EU) 2017/745 on medical devices

MDCG 2020-7: 2020-04: Guidance on PMCF plan template

MDCG 2020-8: 2020-04: Guidance on PMCF evaluation report template

MDCG 2020-3, Rev. 1: 2023-05: Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD

MDCG 2020-6: 2020-04: Guidance on Sufficient Clinical Evidence for Legacy Devices: Background note on the relationship between MDCG 2020-6 and MEDDEV 2.7/1 rev.4 on clinical evaluation

MDCG 2020-5: 2020-04: Guidance on Clinical Evaluation – Equivalence

MDCG 2020-13: 2020-07: Clinical evaluation assessment report template

MDCG 2018-1, Rev.4: 2021-04: Guidance on BASIC UDI-DI and changes to UDI-DI

MDCG 2021-19: 2021-07: Guidance note integration of the UDI within the organization’s quality management system

MDCG 2021-25 Rev.1: 2024-10: Application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

MDCG 2019-14: 2019-12: Explanatory note on MDR codes

EMDN V2.0: 2025-01: European Medical Device Nomenclature (EMDN)

CND: 2020-01: The CND nomenclature – Background and general principles

NBOG_BPG_2009-2: 2009-03: Guideline for Designating Authorities to Define the Notification Scope of a Notified Body Conducting Medical Devices Assessments

MDCG 2021-24: 2021-10: Guidance on classification of medical devices

MDCG 2022-4, Rev.2: 2024-05: Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD

MDCG 2022-21: 2022-12: Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745

MDCG 2023-3, Rev.2: 2025-01: Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2027/746

Standards:

DIN EN ISO 13485: 2021-12: Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016); German version EN ISO 13485:2016 + AC:2018 + A11:2021

DIN EN ISO 14971: 2022-04: Medical devices - Application of risk management to Medical devices (ISO 14971:2019); German version EN ISO 14971:2019 + A11:2021

ISO/TR 24971: 2020-06: Medical devices - Guidance for the use of ISO 14971

DIN EN ISO 15223-1: 2022-02: Medical devices - Symbols for use in the information supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021); German version EN ISO 15223-1:2021

DIN EN ISO 20417: 2022-03: Medical devices - Requirements for information to be provided by the manufacturer (ISO 20417:2021, corrected version 2021-12); German version EN ISO 20417:2021

DIN EN 62366-1: 2021-08: Medical devices - Part 1: Application of fitness for use to medical devices (IEC 62366-1:2015 + COR1:2016 + A1:2020); German version EN 62366-1:2015 + AC:2015 + A1:2020

DIN EN ISO 14155: 2021-05: Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020); German version EN ISO 14155:2020

DIN EN ISO 11737-1: 2021-10: Sterilisation of health care products – Microbiological methods - Part 1: Determination of the population of microorganisms on products (ISO 11737-1: 2018 + Amd 1: 2021); German version EN ISO 11737-1: 2018 + A1: 2021)

DIN EN ISO 11737-2: 2020-07: Sterilisation of health care products – Microbiological methods – Part 2: Sterility testing in the definition, validation and maintenance of a sterilization process. (ISO 11737-1: 2019); German version EN ISO 11737-2: 2020

DIN EN ISO 10993-1: 2021-05: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system (ISO 10993-1:2018, including corrected version 2018-10); German version EN ISO 10993-1:2020.

DIN EN ISO 10993-2: 2023-02: Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2022); German version EN ISO 10993-2:2022

DIN EN ISO 10993-3: 2015-02: Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014); German version EN ISO 10993-3:2014.

DIN EN ISO 10993-5: 2009-10: Biological evaluation of medical devices - Part 5: Tests for in vitro

cytotoxicity (ISO 10993-5:2009); German version EN ISO 10993-5:2009

DIN EN ISO 10993-6: 2017-09: Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016); German version EN ISO 10993-6:2016.

DIN EN ISO 10993-9: 2022-03: Biological evaluation of medical devices - Part 9: Framework for the identification and quantification of potential degradation products (ISO 10993-9:2019); German version EN ISO 10993-9:2021

DIN EN ISO 10993-10: 2023-04: Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021); German version EN ISO 10993-10:2023

DIN EN ISO 10993-11: 2018-09: Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017); German version EN ISO 10993-11:2018.

DIN EN ISO 10993-12: 2021-08: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021); German version EN ISO 10993-12:2021

DIN EN ISO 10993-17: 2024-02: Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device components (ISO 10993-17:2023); German version EN ISO 10993-17:2023

DIN EN ISO 10993-18: 2023-11: Biological evaluation of medical devices - Part 18: Chemical characterisation of materials for medical devices as part of a risk management system (ISO 10993-18:2020 + Amd 1:2022); German version EN ISO 10993-18:2020 + A1:2023

DIN EN 556-1: 2024-09: Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for medical devices sterilized in the final package; German version EN 556-1:2024

DIN EN ISO 17665: 2024-09: Sterilisation of healthcare products - Moist heat - Requirements for the development, validation and control of a sterilisation process for medical devices (ISO 17665:2024); German version EN ISO 17665:2024

DIN EN ISO 20857: 2013-08: Sterilisation of health care products - Dry Heat - Requirements for the development, validation and control of the of the application of a sterilization process for medical devices (ISO 20857:2010); German version EN ISO 20857:2013

DIN EN ISO 11607-1: 2024-02: Packaging for medical devices to be sterilised in the final packaging - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019 + Amd 1:2023); German version EN ISO 11607-1:2020 + A1:2023

DIN EN ISO 11607-2: 2024-02: Packaging for medical devices to be sterilised in the final packaging - Part 2: Validation requirements for forming, sealing and assembling processes (ISO 11607-2:2019 + Amd 1:2023); German version EN ISO 11607-2:2020 + A1:2023

DIN EN 868-2: 2025-09: Packaging for medical devices to be sterilized in the final packaging – Part 2: Sterilisation packaging – Requirements and test methods; German version EN 868-2:2025

DIN EN 868-5: 2019-03: Packaging for terminally sterilized medical devices - Part 5: Sealable transparent pouches and tubes made of porous materials and plastic laminated film - Requirements and test methods; German version EN 868-5:2018

DIN EN 17141: 2021-02: Cleanrooms and associated cleanroom areas - Biocontamination control; German version EN 17141:2020

DIN EN ISO 14644-1: 2016-06: Cleanrooms and associated cleanroom environments - Part 1: Classification of air cleanliness based on particle concentration (ISO 14644-1:2015); German version EN ISO 14644-1:2015

DIN EN ISO 14644-2: 2016-05: Cleanrooms and associated cleanroom areas - Part 2: Monitoring to demonstrate cleanroom performance with respect to air purity using particle concentration (ISO 14644-2:2015); German version EN ISO 14644-2:2015

DIN EN ISO 14644-3: 2020-08: Cleanrooms and associated cleanroom areas - Part 3: Test methods (ISO 14644-3:2019, corrected version 2020-06); German version EN ISO 14644-3:2019.

DIN EN ISO 14644-4: 2023-04: Cleanrooms and associated cleanroom areas - Part 4: Planning, design, construction and initial commissioning (ISO 14644-4:2022); German version EN ISO 14644-4:2022

DIN EN ISO 14644-5: 2005-03: Cleanrooms and associated cleanroom areas - Part 5: Operation (ISO 14644-5:2004); German version EN ISO 14644-5:2004

DIN EN ISO 14644-7: 2005-01: Cleanrooms and associated cleanroom environments - Part 7: SD modules (clean air bonnets, glove boxes, isolators and minienvironments) (ISO 14644-7:2004); German version EN ISO 14644-7:2004

DIN EN ISO 14644-8: 2022-10: Cleanrooms and associated cleanroom areas - Part 8: Chemical air cleanliness assessment (ACC) (ISO 14644-8:2022); German version version EN ISO 14644-8:2022

DIN EN ISO 14644-9: 2022-10: Cleanrooms and associated cleanroom areas - Part 9: Evaluation of of particulate surface cleanliness (ISO 14644-9:2022); German version version EN ISO 14644-9:2022

DIN EN ISO 14644-10: 2022-10: Cleanrooms and associated cleanroom areas - Part 10: Assessment of chemical surface cleanliness (ISO 14644-10:2022); German version EN ISO 14644-10:2022

DIN EN ISO 14644-13: 2017-11: Cleanrooms and associated cleanroom areas - Part 13: Cleaning of surfaces to achieve defined cleanliness levels with respect to particle and chemical classifications (ISO 14644-13:2017); German version EN ISO 14644-13:2017.

DIN EN ISO 14644-14: 2017-01: Cleanrooms and associated cleanroom environments - Part 14: Evaluation of cleanroom suitability of equipment by airborne particle concentration (ISO 14644-14:2016); German version EN ISO 14644-14:2016.

DIN EN ISO 14644-15: 2025-03: Cleanrooms and associated cleanroom environments - Part 15: Assessment of cleanroom suitability of equipment and materials using air and surface chemical concentrations (ISO 14644-15:2017); German version EN ISO 14644-15:2017.

DIN EN ISO 14630: 2025-03: Non-active surgical implants – General requirements (ISO 14630:2024); German version EN ISO 14630:2024

DIN EN ISO 14937: 2010-03: Sterilization of health care products - General requirements for the characterization of a sterilizing agent and for the development, validation and control of the use of a sterilization process for medical devices (ISO 14937:2009); German version EN ISO 14937:2009

DIN EN ISO 16672: 2022-05: Ophthalmic implants - Ocular endotamponades (ISO 16672:2020); German version EN ISO 16672:2021

DIN EN ISO 3166-1: 2020-12: Codes for the names of countries and their subdivisions - Part 1: Codes for country names (ISO 3166-1:2020); English version EN ISO 3166-1:2020

DIN ISO 10002: 2019-07: Quality management - Customer satisfaction - Guidance for complaint handling in organizations (ISO 10002:2018)

DIN EN ISO 11138-4: 2017-07: Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes (ISO 11138-4:2017); German version EN ISO 11138-4:2017

DIN EN ISO 11138-3: 2017-07: Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017); German version EN ISO 11138-3:2017.

DIN EN ISO 80369-7: 2021-08: Small diameter connectors for liquids and gases in medical applications – Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7: 2021); German version EN ISO 80369-7: 2021

DIN EN 285: 2021-12: Sterilisation - Steam sterilisers - Large sterilisers; German version EN 285:2015 +A1:2021

ASTM D4169-23e1: 2024-03: Standard Practice for Performance Testing of Shipping Containers and Systems

ASTM D4332-22: 2022-06: Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

ASTM D5276-19(2023): 2023-10: Standard Test Method for Drop Test of Loaded Containers by Free Fall

ASTM D642-25: 2025-04: Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads

ASTM D4728-17(2022): 2022-05: Standard Test Method for Random Vibration Testing of Shipping Containers

ASTM D6344-04(2024): 2024-10: Standard Test Method for Concentrated Impacts to Transport Packages

ASTM F-1886/F1886M (2024): 2024-11: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

ASTM F3039-23: 2023-06: Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration

ASTM F88/F88M-23: 2023-08: Standard Test Method for Seal Strength of Flexible Barrier Materials

ASTM F1929-23: 2023-12: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

ASTM D6499-24: 2024-06: Standard Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products

ASTM F1980-16: 2021-12: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

A summary of the safety and clinical performance of the device, intended for patients, is given below.

Summary of safety and clinical performance

Document revision: 10

Date issued: 09/2025

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1. Device identification and general information

o Device trade name

Siluron® 1000 / 2000 / Xtra / 5000

o Manufacturer; name and address

Fluoron® GmbH
Gesellschaft für hochreine Biomaterialien
Magirus-Deutz-Straße 10
89077 Ulm
Germany

www.fluoron.de
Email: info@fluoron.de
T +49 (0) 731 205 5997 0
F +49 (0) 731 205 5997 28

o Basic UDI-DI

4260160455105G

o Year when the device was first CE-marked

Product	Year
Siluron® 1000	2002
Siluron® 2000	2008
Siluron® 5000	2002
Siluron® Xtra	2013

2. Intended use of the device

o Intended purpose

Siluron® 1000 / 2000 / Xtra / 5000 are sterile medical devices composed of ultrapure silicone oil (polydimethylsiloxane). Siluron® 1000 / 2000 / Xtra / 5000 are used as postoperative long-term endotamponades in the field of ophthalmic surgery.

o Indications and intended patient groups

Siluron® 1000 / 2000 / Xtra / 5000 are intended only for ocular application. Siluron® 1000 / 2000 / Xtra / 5000 are used for the treatment of severe cases of retinal detachment, especially for:

- Retinal detachments with giant tears
- Retinal detachments with proliferative vitreoretinopathy (PVR)
- Retinal detachments in cases of proliferative diabetic retinopathy (PDR)
- Traumatic retinal detachments

Siluron® 1000 / 2000 / Xtra / 5000 is also used as a tamponade in macular hole surgery.

Intended patient population: Patients requiring surgical treatment of severe retinal detachment or surgical treatment of a macular hole. Use in pregnant women, nursing mothers, and children is not recommended.

o Contraindications

Siluron® 1000 / 2000 / Xtra / 5000 are not permitted to be used in patients who are hypersensitive to silicone oil or wear a silicone intraocular lens (IOL). In addition, laser coagulation or cryotherapy are not permitted in eyes filled with Siluron® 1000 / 2000 / Xtra / 5000.

3. Device description

o Device description and material/substances in contact with patient tissues

Siluron® 1000/2000/Xtra/5000 are sterile colourless, homogeneous liquids that consist of ultrapure polydimethylsiloxane. Polydimethylsiloxane is commonly used in retinal surgery and belongs to chemical compounds referred as silicone oils. Silicone oil is an optically clear, viscous, hydrophobic, and lipophilic liquid.

Siluron® 1000/2000/Xtra/5000 are well-established devices and are used as a long-term tamponade for the treatment of severe cases of retinal detachment, especially for retinal detachments with giant tears, retinal detachments with proliferative vitreoretinopathy, retinal detachments in cases of proliferative diabetic retinopathy or traumatic retinal detachments. Siluron® 1000 / 2000 / Xtra / 5000 is also used as a tamponade in macular hole surgery.

Siluron® silicone oils can be subdivided into the standard Siluron® 1000 and 5000 (named according to their approximate viscosity of 1,000 and 5,000 mPas, respectively) and the oil blends Siluron® 2000 and Xtra. Siluron® 2000 consists of 95% Siluron 1000 and 5% of a long chain high molecular weight silicone oil of about 2.5 Mio mPas (Siluron Xtra: 90% Siluron® 1000 and 10% high molecular weight silicone oil, 2.5 Mio mPas). By adding 10% silicone oil with 423 kDa, the shear viscosity of Siluron® Xtra doubles to mean values of around 4,437 mPas (at 25 s^{-1}) as compared to Siluron® 2000 with 2,213 mPas (mean value at 25 s^{-1}). However, this value is lower than the shear viscosity of the 5,000 mPas silicone oil with e.g. 5,052 mPas. This provides Siluron® 2000 and Siluron® Xtra with a high resistance to emulsification compared to standard silicone oils like Siluron® 1000 and 5000 while maintaining good applicability.

o Information about medicinal substances in the device, if any

Siluron® 1000/2000/Xtra/5000 contain no biologically active components, are chemically and physiologically inert, and non-toxic. The medical devices are not radioactive, have no pharmacological effect, and contain no medicinal products or tissue or blood products of animal or human origin.

o Description of how the device is achieving its intended mode of action

Siluron® 1000/2000/Xtra/5000 are used as long-term tamponades for retinal reattachment as well as in macular hole surgery.
With the exception of eyes having a complex baseline situation, the indwelling time for Siluron® 1000/2000/Xtra/5000 should be kept as short as possible and limited to at most 6 months.

o Description of accessories, if any

No specific accessories are necessary for the application of Siluron® 1000/2000/Xtra/5000 according to intended use.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

o How potential risks have been controlled or managed

If you, as a patient, believe that you are experiencing an adverse reaction related to the product or its use, so please contact Fluoron GmbH immediately via e-mail *complaints@fluoron.de* or the competent authority of your country.

On the basis of the continuous surveillance of the medical devices on the market (post-market surveillance), potential risks that may arise in connection with the use of the Fluoron device are reviewed. Furthermore, existing risks are reduced by implementing appropriate risk control measures to acceptable residual risks, if possible.

o Remaining risks and undesirable effects

Side effects / complications associated with vitrectomy together with the application of Siluron® 1000/2000/Xtra/5000 and identified via clinical literature data (resulted from a systematic review of scientific literature) and via complaints reported the Fluoron GmbH in context of Siluron® device application are described in the following:

Side effects and complications	**Expected frequency**	**Time of occurrence (intraoperative, postoperative)**
Anterior eye segment complications (e.g. cataract *(clouding or loss of transparency of the lens in the eye)*, corneal complications (*disorders of the outermost layer of the eyeball in the area in front of the lens))*	> 1 of 100000 and ≤ 1 of 10000	postoperative
Decrease in visual acuity to vision loss (e.g., blurred vision)	> 1 of 100000 and ≤ 1 of 10000	postoperative
Emulsification *(Separation of small stable droplets from a large silicone oil bubble; happens continuously at the (phase) boundary between oil and water)*	> 1 of 10000 and ≤ 1 of 1000	postoperative
Decreased or increased intraocular pressure *(an abnormally low or high pressure in the eye often causes damage of the optic nerve)*	> 1 of 10000 and ≤ 1 of 1000	postoperative
Retinal re-detachment (*detachment of the retina, possibly caused by new retinal breaks or the traction of the original tears*)	> 1 of 100000 and ≤ 1 of 10000	intraoperative (iatrogenic retinal tear/peripheral tractional detachment) or postoperative (redetachment)
Intraocular inflammation *(Inflammation in the eye)*	> 1 of 100000 and ≤ 1 of 10000	postoperative
New membrane formation *(e.g. epiretinal membrane formation)*	> 1 of 100000 and ≤ 1 of 10000	postoperative

Side effects and complications	Expected frequency	Time of occurrence (intraoperative, postoperative)
Migration of silicone oil (*e.g., silicone oil migrates under the retina, silicone oil migrates under the conjunctiva*)	> 1 of 10000 and ≤ 1 of 1000	intraoperative (subretinal SO) or postoperative (subconjunctival SO)

Abbreviations: SO – silicone oil, AC – anterior chamber, ERM – epiretinal membrane, IOP – increased intraocular pressure

All the risks (side effects / complications) described in the table above correspond risks associated with vitrectomy together with the application of a silicone oil endotamponade such as Siluron® 1000/2000/Xtra/5000.
Further risks in context of Siluron® application were identified within the clinical literature data. These risks are general complications due to the surgical procedure without a direct relation to the Siluron® application (e.g. haemorrhage), or are already known as contraindication (allergic reactions) or were not caused by the silicone oil itself but by other complications that arose (e.g. early silicone oil removal, which was released by existence of other complications).

o Warnings and precautions for patients

- Use in pregnant women, nursing mothers and children is not recommended.
- The indwelling time of the device should be kept as short as possible and limited to the recommended duration of use. A short length of indwelling time can reduce potential side effects and complications.
- Silicone oil could migrate out of the eye and could form lesions in the conjunctiva or eyelid.
- Before Siluron® 1000/2000/Xtra/5000 are permitted to be instilled in the eye, any heavy liquids, e.g., perfluorocarbons of any kind, must be completely removed from the vitreous chamber.

o Summary of any field safety corrective action, (FSCA including FSN) if applicable

In the current post-market surveillance period (2021 until quarter 3/2025) a field safety corrective action (FSCA) concerning some Siluron® batches was performed by Fluoron GmbH:
In October 2023, cloudiness of the Siluron® device in the patient's eye was observed during the postoperative clinical follow-up phase. This cloudiness presents itself as a temporary restriction of the patient's vision. Droplets as in emulsification could not be observed. Further, the opacity has no effect on the function of the silicone oil as a tamponade of the retina. The patient's temporary visual limitation remains until the silicone oil is explanted and disappears as soon as the oil is removed. Because a third complaint received by Fluoron GmbH with this same failure (postoperative cloudy silicone oil in patient's eye) and simultaneously this reported turbidity leads to user uncertainty, the Fluoron GmbH decided to issue a voluntary recall. The scope of this recall was limited to certain Siluron batches where the same raw material batches were used and were subject to the same manufacturing processes. As root cause of the postoperative cloudy silicone oil in the patient's eye an undesirable admixture (most probably silicic acid) in the silicone oil raw material could be identified, caused by the supplier of the polydimethylsiloxane raw material. To avoid a further case of such an adverse event, the silicone oil raw material specification was expanded by the "turbidity" measurement.

5. Summary of clinical evaluation and post-market clinical follow-up

o Clinical background of the device

Silicone oils are used as tamponades in eye surgeries. They serve for treatment of severe cases of retinal detachment. Here, a good tamponade effect is restricted to upper retina.
The oils are the standard medium of long-term tamponades after retina is re-attached.
Mixed and unmixed silicone oils exist. The mixed oils are good injectable and show a low rate of emulsification. If an oil emulsifies, this can lead to inflammation. So, mixed oils are preferable.
Further, silicone oil tamponades are used to close macular holes. The macular hole closure rate depends on many factors, like the macular hole type.

o The clinical evidence for the CE-marking

Silicone oil tamponades have been successfully used as tamponades in ophthalmic surgery for many decades. From a clinical perspective, no other long-term tamponade has been as well studied as silicone oil, and the clinical performance and safety of this product are well documented in publications. This means that silicone oil has become a standard tamponade.

The Fluoron products Siluron® 1000/2000/Xtra/5000, like all other silicone oil products used as tamponade in ophthalmic surgery, consist of the same chemical substance polydimethylsiloxane. Therefore, the silicone oil products do not differ in terms of materials or many physicochemical properties. Due to the different number of repeating siloxane units, the molecular weights and viscosities of the silicone oils change, but the other properties important for clinical use on the eye as a long-term tamponade remain unchanged.

The clinical evidence (safety and clinical performance) of the products Siluron® 1000/2000/Xtra/5000 is based on state-of-the-art data, clinical literature data, usability evaluation data and the post-market surveillance data.

o Safety

Based on the publications including state-of-the-art data and clinical data on treatment of retinal detachment and macular hole treatment, the clinical performance and safety of Siluron® 1000/2000/Xtra/5000 were verified.
Further, the following risks (side effects and complications) associated with vitrectomy together with the application of Siluron® 1000/2000/Xtra/5000 were identified via clinical literature data and via complaints reported the Fluoron GmbH in context of Siluron® device application:
anterior eye segment complications, decrease in visual acuity to vision loss, emulsification, decreased or increased intraocular pressure, retinal re-detachment, intraocular inflammations, new membrane formation and migration of silicone oil.
The two risks “migration of silicone oil” and “new membrane formation” were identified as new side effects within the scope of the researched clinical literature data of Siluron® 1000/2000/Xtra/5000. The list of side effects and complications in the instructions for use of the Siluron® devices was updated accordingly.
Furthermore, all these side effects / complications were evaluated within the Siluron® risk assessment, and corresponding risk control measures were implemented. The risk evaluation of Siluron® showed that the benefit still outweighs the possible risks in context of a Siluron® 1000/2000/Xtra/5000 application. So, if the Siluron® silicone oils are applied according to the intended use as specified in the instructions for use, a safe application of these tamponades can be guaranteed.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

o General description of therapeutic alternatives

Since 1960, researchers have tried to find adequate substitutes to replace the physical and biological functions of the vitreous body. Different currently available tamponade agents able to fulfil this function are summarised below:

Gas	Silicone oil
Small volumes of undiluted gas are typically used for pneumatic retinopexy, larger volumes for pars plana vitrectomy. Sulphur hexafluoride (SF_6), perfluoroethane (C_2F_6) and perfluoropropane (C_3F_8) are the most commonly used gases. SF6 exerts an effect for 1 to 2 weeks, whereas C3F8 persists for 6 to 8 weeks. Due to their very low specific gravities they have a much greater buoyancy than silicone oils. Because the effect is greatest at the upper side of the bubble, this results in a good tamponade of the upper retina, while the patient is in an upright position, but a less effective support of the lower retina. The advantage of these gases is that they are slowly removed via the blood and replaced with aqueous humour. This makes it unnecessary to perform another surgical procedure to remove the gas from the eye, as in the case of the silicone oils. These gases are used in less complicated cases	Silicone oils have been used to act as internal tamponades in vitreoretinal surgery procedures for more than 40 years. Their use as intra-operative tool to stabilise the retina can be adopted in difficult cases of retinal detachment such as those complicated with proliferative vitreoretinopathy, giant retinal tears, and penetrating ocular trauma. With the introduction of pars plana vitrectomy, silicone oils became also the standard medium for post-operative long-term tamponade in the vitreous cavity following re-attachment of the retina. Silicone oil agents are used to ensure retinal adherence following retinopexy for the time necessary to generate a permanent seal, to control intraocular haemorrhages, and to maintain intraocular pressure. As with gas, the good tamponade effect of silicone oils is restricted to the superior retina when the patients head is in an upright position. The indwelling time for Siluron®

Gas	Silicone oil
due to their shorter indwelling times in the eye. Due to the fact that gases expand rapidly with any drop in air pressure, travel by plane and stay at higher elevations are contraindicated in cases where the vitreous cavity has been instilled with gas.	1000/2000/Xtra/ 5000 should be kept as short as possible and limited to at most 6 months.

7. Suggested training for users

Siluron® 1000/2000/Xtra/5000 devices are prepared and used exclusively by qualified personnel for intraocular surgery. They have completed a medical degree and the corresponding specialist training. The users have experience with comparable products, because silicone oil tamponades belong to the usual aids for the treatment of severe cases of retinal detachment and macular hole surgery.