Summary of safety and clinical performance OVOIL™

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 (IFU) 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	OVOIL™
1.2	Manufacturer's name and address	Vitrolife Sweden AB, Gustaf Werners gata 2, SE-421 32 Västra Frölunda, Sweden
1.3	Manufacturer's single registration number (SRN)	SE-MF-000002389
1.4	Basic UDI-DI	735002591AAOE6
1.5	Global Medical device nomenclature code	44046
1.6	Class of device	III
1.7	Year when the first certificate (CE) was issued covering the device	2002
1.8	Authorized representative if applicable; name and SRN	Not applicable
1.9	NB's name (the NB that will validate the SSCP) and the NB's single identification number	DNV Product Assurance AS Veritasveien 1, 1363 Høvik, Norway 2460

2 Intended use of the device

2.1 Intended purpose

OVOIL is a medical device intended for use in Assisted Reproductive Technology (ART) as an oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.

2.2 Indication(s) and target population(s)

The Indication for use of the OVOIL is "oil for covering of medium during in vitro fertilisation and micro-manipulation procedures". The intended target group is an adult or reproductive-age population that undergoes IVF treatment or fertility preservation, respectively.

2.3 Contraindications and/or limitations

None.

3 Device description

3.1 Description of the device

OVOIL is a sterile-filtered light paraffin oil, intended to cover medium during in vitro fertilisation (IVF) and micro-manipulation procedures. Based on its Indication for Use, OVOIL is not intended to have patient contact. The

device is ready to use after equilibration at +37°C and 5% CO_2, 6% CO_2 or ambient atmosphere, depending on the intended use. OVOIL is delivered in a 100 mL glass type 1 borosilicate bottle which is sterilized by dry heat sterilization and covered with a polybutylene terephthalate - 30% glass fibre reinforced cap (Figure 1).

Figure 1. Picture of OVOIL

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

There have been no previous versions of OVOIL.

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

Not applicable.

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

General equipment and sterile non-toxic disposables for the IVF lab including CO_2 incubator.

4 Risks and warnings

4.1 Residual risks and undesirable effects

All known and foreseeable risks and undesirable side-effects associated with the use of OVOIL were evaluated and mitigated as much as possible during risk management. There are no risks with the potential to affect the patient or the end user's health. All the identified risks affect the gametes, or the embryos are acceptable after risk control measures when weighed against the benefits to the patient. As part of risk mitigation, all oil raw material is quality tested using a highly sensitive mouse embryo assay (MEA) with subsequent oil filtration and each produced batch is tested prior to its release to the market. In addition, OVOIL is manufactured in glass bottles to circumvent any possible interactions with, or extractions from, plastics. Clear information materials (labelling, package inserts, manuals, etc.) are provided.

4.2 Warnings and precautions

The precautions that are related to the use of OVOIL are:

- Discard product if bottle integrity is compromised. Do not use OVOIL if it appears cloudy.
- Re-use may result in microbiological contamination and/or property changes in the product.
- To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique.
- The risks of reproductive toxicity and developmental toxicity for IVF media, including Vitrolife's IVF media, have not been determined and are uncertain.

- Any serious incident that has occurred in relation to the device should be reported to the manufacturer.
- Not for injection.
- Discard product according to standard clinical practice for medical hazardous waste when the procedure is finished.
- Caution: Federal (US) law restricts this device to sale by or on the order of a physician or practitioner trained in its use (Rx only).

Additional information related to the use of the device can be found in the package insert.

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

No FSCAs have been taken for OVOIL during its lifecycle.

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

5.1 Summary of clinical data related to equivalent device, if applicable

Not applicable

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not applicable.

5.3 Summary of clinical data from other sources, if applicable

A systematic literature search was performed during the clinical evaluation of OVOIL to identify the clinical data including the use of the device. Outcomes (fertilization rates, cleavage rates, and blastocyst development rates) reported by recent articles from 2023 after the use of OVOIL as an oil overlay during IVF and micromanipulation procedures are summarized in Table 1. These outcomes align with the competency values described in the consensus report, confirming the performance and safety of OVOIL.

Table 1. An overview of outcomes after the use of OVOIL

Reference	Insemination method	FR, %	Cleavage rate, %	Blastocyst development rates, %
[1] Caddy et al. 2023	ICSI /PIEZO-ICSI	45.3*/ 61.9	NR	NR
[2] Esmaeilian et al. 2023	ICSI	81-87	NR	35-41
[3] Le et al. 2023	PICSI / ICSI	72.80/ 75.33	95.13/ 96.04	52.68/ 57.89
[4] Liu et al. 2023	IVF	92.0	NR	53.2
[5] Nobrega et al. 2023	ICSI	78.8-79.3	98.5-99.1	NR
[6] Pai et al. 2023	IVF / ICSI	76.4-79.0	NR	53.6-63.5
[7] Prasetiawati et al. 2023	IVF / ICSI	59-64	NR	NR
[8] Viganò et al. 2023	IVF	75.0-77.7	NR	NR
[9] Anis et al. 2024	ICSI	72.6-73.4	94.7-99.1	57.6-59.2
[10] Brouillet et al. 2024	IVF / ICSI	75.6-78.3	NR	NR

Reference	Insemination method	FR, %	Cleavage rate, %	Blastocyst development rates, %
[11] Chu and Fu 2024	IVF / ICSI	NR	97.6-97.7	59.9-62.0
[12] Escudé-Logares et al. 2024	ICSI	71.7-75.0	NR	57.5-61.0
[13] Han et al. 2024	IVF / ICSI	85.1-87.8	NR	NR
[14] Mostinckx et al. 2024	ICSI	64.6*-76.5	NR	NR
[15] Nguyen Thanh et al. 2024	ICSI	77.81-75.58	NR	40.16-41.26
[16] Park et al. 2024	ICSI	80.5	99.6	NR
[17] Qiu et al. 2024	Short-term IVF/R-ICSI/ICSI	88.41/77.84/87.25	97.98/97.02/98.95	NR
[18] Shioya et al. 2024	PIEZO-ICSI	67.82-72.99	95.35-97.75	31.32-43.57
[19] Sun et al. 2024	IVF	72.3-77.9	95.2-95.6	NR
[20] Taniguchi et al. 2024	IVF	67.6-68.5	NR	77.5-79.4
[21] Venturas et al. 2024	IVF / ICSI	76.3	NR	NR
[22] Vergara et al. 2024	ICSI/PiWA-ICSI	73.33-88.12	NR	NR
[23] Williams et al. 2024	ICSI /HA-ICSI	68.4/64.7	NR	NR
[24] Wouters et al. 2024	ICSI	79.9-80.5	NR	NR

* Caddy et al. 2023 included patients who had previous conventional ICSI cycles with poor outcomes. In Mostinckx, 2024, lower FR came from IVM cycle.

Successful clinical outcomes including clinical pregnancy rates (CPRs), and live birth rates (LBRs) were also reported after a treatment that included the use of OVOIL.

5.4 An overall summary of the clinical performance and safety

According to the Indication for Use, OVOIL is an oil for covering of medium during in vitro fertilisation and micro-manipulation procedures. By covering the culture medium, the device supports the culture conditions by minimizing changes in pH, temperature and osmolality and thus support the procedures. The validation tests conducted by Vitrolife confirm that the device maintains pH, temperature, and osmolality in the culture medium. This is further confirmed by data from scientific literature. The primary endpoint after the use of OVOIL is fertilization. The fertilization rates reported after the use of OVOIL were in line with the ESHRE competency values published in 2017 at the Vienna Consensus [25]. Likewise, the IVF outcomes (CPRs and LBRs) following a treatment that included OVOIL align with the yearly European results published by ESHRE [26]. There are no indications of any negative effects resulting from the use of OVOIL. The risk management has been effective; all residual risks with the potential to affect the gametes/embryos are acceptable. Data from PMS and PMCF activities confirm the safety and performance of the device and ensure the continued acceptability of the benefit-risk profile. No emerging risks or previously unknown side-effects were identified. No known side-effects and/or contraindications were found. No off-label use or misuse of the device was identified.

5.5 Ongoing or planned post-market clinical follow-up

There are no ongoing or planned PMCF studies for OVOIL.

6 Possible diagnostic or therapeutic alternatives

ART is a treatment option for patients failing to conceive naturally as well as patients who have tried other treatments such as medications and surgical procedures without success. Hence, there are no therapeutic alternatives for patients at this stage.

Devices with similar intended use are available in the European Union or other international markets. Currently, there is no consensus on which oil is superior, and choices of a specific laboratory might be based on oil viscosity, the impact of dish preparation techniques, or embryologist preference [27].

In a recent study comparing 13 marketed oils, 2 out of the 13 oil samples were identified as embryo-toxic by applying the MEA protocol with increased sensitivity for toxicity detection [28]. Oils are essential components of culture systems. Their original quality and composition, storage, handling, and use can affect embryo development with significant efficiency and safety implications [29].

7 Suggested profile and training for users

The end user (IVF professional) is expected to be trained and qualified within ART field to understand the Indication for Use of OVOIL. Since no special design or safety concerns were identified for OVOIL, there is no specific training required for the end-users.

8 Reference to any harmonised standards and common specifications applied

- Medical Devices Regulation (EU) 2017/745 (MDR)
- EN ISO 14971:2019/A11:2021. Medical Devices. Application of risk management to medical devices. 31 December 2021.
- ISO/TR 20416:2020. Medical devices — Post-market surveillance for manufacturers. July 2020
- EN ISO 20417:2021. Medical devices — Information to be supplied by the manufacturer. December 2021
- MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies. April 2020
- MDCG 2019-9 Rev.1. Summary of safety and clinical performance. A guide for manufacturers and notified bodies. March 2022

The conformity assessment procedure follows Annex IX in the MDR.

9 Revision history

Version	Date issued	Description	Revision validated by the Notified Body
v.1.0	2021-08-13	Initial version of SSCP for OVOIL (REP-4043-v.1.0)	
v.2.0	2021-10-12	Correction of statement regarding device contact in 3.1 device description section. No other changes	
v.3.0	2022-04-03	Annual update of SSCP for OVOIL (REP-4043)	
v.4.0	2023-02-23	Edits based on DNV comments	☑ Yes Validation language: English
v.5.0	2023-12-08	Annual update in 2023	
v.6.0	2024-11-12	Annual update in 2024	

Version	Date issued	Description	Revision validated by the Notified Body
v.7.0	See publish date	Remove the comparison table between similar devices in Section 6 and adjust the citation format.	☑ Yes Validation language: English

10 References

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