Summary of safety and clinical performance OVOIL HEAVY™

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 HEAVY™
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 (GMDN) code	44046
1.6	Class of device	III
1.7	Year when the first certificate (CE) was issued covering the device	2020
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 HEAVY 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 OVOIL HEAVY 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 HEAVY is the world´s first synthetically derived paraffin oil developed specifically for clinical IVF. It is a sterile-filtered high-viscosity oil that is ready to use after equilibration at +37°C in CO_2-incubator or ambient atmosphere, depending on the intended use. OVOIL HEAVY is delivered in a 100 mL glass type 1 borosilicate dry heat sterilized bottle with a polybutylene terephtalate - 30% glass fibre reinforced cap (Figure 1).

Figure 1. Picture of OVOIL HEAVY

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

None.

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

None.

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 HEAVY were identified, evaluated, and mitigated as far 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/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 HEVY is manufactured in glass bottles to circumvent any possible

interactions with, or extractions from, plastics. Additionally, information materials (labelling, package insert, manual etc.) are made as clear as possible and Vitrolife organizes education programs for users.

4.2 Warnings and precautions

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

- Discard product if bottle integrity is compromised. Do not use OVOIL HEAVY if it appears cloudy.
- To avoid contamination, Vitrolife strongly recommends that bottle should be opened and used only with aseptic technique.
- The risks of reproductive toxicity and developmental toxicity for IVF products, including Vitrolife's IVF products, 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

None.

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

The fertilization rates (FR) reported by recent publications after the use of OVOIL HEAVY as an oil overlay during IVF and micromanipulation procedures are summarized in Table 1. Additionally, clinical experience data including 344 patients who underwent IVF treatment demonstrated that OVOIL HEAVY is at least as efficient in sustaining fertilization and embryo development as other commercial oils. Comparable pregnancy outcomes were also shown between OVOIL HEAVY and another oil overlay from a different supplier (Vitrolife data on file, 2021).

Table 1. An overview of Fertilization Rate after the use of OVOIL HEAVY

Reference	Population	Intervention	FR, %
[1] Mendola et al. 2023	115 patients, 1,997 oocytes	ICSI	85.4
[2] Kathryn Gurner et al. 2023	554 patients	IVF	53.9
		ICSI	61.2
Clinical experience data	344 patients, 1,593 oocytes	Not mentioned	72.0 (59.5-90.3)*

Note: In reference to Kathryn Gurner, 2023, published as a conference abstract, no detailed information on the IVF procedure was provided. Therefore, it is unclear why the fertilization rates (FR) reported in this abstract are lower than the competency values reported by ESHRE in the 2017 Vienna consensus [3]. If FRs are calculated on all collected oocytes, the numbers are lower. * Range

5.4 An overall summary of the clinical performance and safety

Clinical experience data and scientific literature data of OVOIL HEAVY support the safety and performance of OVOIL HEAVY. There are no indications of any negative effects resulting from the use of the device. Data from PMS and PMCF activities add support to the safety and performance of OVOIL HEAVY. The risk management for OVOIL HEAVY has been effective. The overall residual risks are acceptable. No further risks have been identified and the benefit-risk profile is acceptable in accordance with the current knowledge/state of the art.

5.5 Ongoing or planned post-market clinical follow-up

There are no ongoing or planned PMCF studies for OVOIL HEAVY.

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 [4].

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 [5]. 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 [6].

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 HEAVY. Since no special design or safety concerns were identified for OVOIL HEAVY 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 is performed according to Annex IX in the MDR.

9 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
v.1.0	2021-10-12	Initial version of SSCP for OVOIL HEAVY (REP-4383-v.1.0)	
v.2.0	2022-05-11	Periodic update of SSCP for OVOIL HEAVY (REP-4383-v.2.0)	
v.3.0	2023-02-21	Edits based on DNV comments	
v.4.0	2023-06-02	Reference to equivalent device removed	☑ Yes Validation language: English
v.5.0	2023-12-14	Annual update in 2023	
v.6.0	2025-02-25	Annual update in 2024	
v.7.0	See publish date	Remove the comparison table between similar devices in Section 6 and adjust citation format	☑ Yes Validation language: English

10 References

1. Mendola, R., et al., *P-157 Improved embryo development and clinical outcome using bicarbonate buffer as the oocyte holding medium during Intracytoplasmic sperm injection (ICSI) compared to MOPS buffer.* Human Reproduction, 2023. 38(Supplement_1): p. dead093. 520.
2. Kathryn Gurner, H., et al., *#288 : Comparison of OVOIL and OVOIL HEAVY in the Clinical IVF Laboratory on Fertilization, Blastocyst Utilization and Transfer Outcomes.* Fertility & Reproduction, 2023. 05(04): p. 656-656.
3. ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine, *The Vienna consensus: report of an expert meeting on the development of ART laboratory performance indicators.* Reprod Biomed Online, 2017. 35(5): p. 494-510.
4. Sciorio, R. and P. Rinaudo, *Culture conditions in the IVF laboratory: state of the ART and possible new directions.* Journal of Assisted Reproduction and Genetics, 2023. 40(11): p. 2591-2607.
5. Mestres, E., et al., *Characterization and comparison of commercial oils used for human embryo culture.* Hum Reprod, 2022. 37(2): p. 212-225.
6. Scarica, C., et al., *Use of mineral oil in IVF culture systems: physico-chemical aspects, management, and safety.* J Assist Reprod Genet, 2022. 39(4): p. 883-892.

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