Summary of safety and clinical performance G-MOPS/G-MOPS PLUS™

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	G-MOPS/G-MOPS PLUS™
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	735002591AAHDQ
1.5	Global Medical Device Nomenclature (GMDN) code	44046
1.6	Class of device	Class III
1.7	Year when the first certificate (CE) was issued covering the device	G-MOPS CE-marked in 2004 and G-MOPS PLUS CE-marked in 2007
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

G-MOPS and G-MOPS PLUS are medical devices intended for use in Assisted Reproductive Technology (ART). G-MOPS is a medium for oocyte collection and for handling and manipulating oocytes and embryos in ambient atmosphere. G-MOPS PLUS is a medium for handling and manipulating oocytes and embryos in ambient atmosphere.

2.2 Indication and target population

G-MOPS: Medium for oocyte collection and for handling and manipulating oocytes and embryos in ambient atmosphere.

G-MOPS PLUS: Medium for handling and manipulating oocytes and embryos in ambient atmosphere.

The intended target group for both G-MOPS and G-MOPS PLUS is an adult or reproductive-age population that undergoes *in vitro* fertilization treatment or fertility preservation.

2.3 Contraindications and/or limitations

G-MOPS/G-MOPS PLUS contains gentamicin. Do not use in patients with known hypersensitivity/allergy to the component.

3 Device description

3.1 Description of the device

G-MOPS is MOPS buffered, physiological salt solution containing gentamicin and is ready to use after equilibration at +37˚C and ambient atmosphere. The device is intended to provide suitable physiological conditions in oocyte collection, handling and manipulation of oocytes and embryos in ambient atmosphere. G-MOPS will have contact with patient when the device is used for oocyte collection. G-MOPS is protein free and the device should not be supplemented with HSA-solution™ (Human serum albumin (HSA) from Vitrolife) when used for oocyte collection. G-MOPS can be used for oocyte and embryo manipulation after the addition of HSA-solution™. G-MOPS has a shelf life of 25 weeks from the date of manufacture.

G-MOPS PLUS is MOPS buffered, physiological salt solution containing HSA and gentamicin and is ready to use after equilibration at +37˚C. Based on the Indication for Use, G-MOPS PLUS will not have contact with patient. G-MOPS PLUS has a shelf life of 21 weeks from the date of manufacture.

G-MOPS and G-MOPS PLUS are stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis. Media are sterile filtered using aseptic technique and are sold in PETG bottles (presterilized with gamma irradiation) with tamper evident seal. Media bottles can be used for up to two weeks after first opening.

Based on regulatory guidelines, the medicinal components present in G-MOPS is gentamicin and that in G-MOPS PLUS are gentamicin and HSA.

Figure 1. Picture of G-MOPS and G-MOPS PLUS

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

Previous version of G-MOPS/G-MOPS PLUS were G-MOPS version 3 and G-MOPS PLUS version 3, respectively. Previous versions were part of Vitrolife G III Series media which had penicillin G as an antibiotic. In 2007, Vitrolife shifted from penicillin G to gentamicin due to the greater longevity of

gentamicin. In addition to this change, the current version has lipoic acid as an antioxidant component to protect oocytes and embryos from free oxygen radicals. The previous versions of G-MOPS/G-MOPS PLUS are not sold on the market.

NOTE: All the data presented in this document apply to the current version of G-MOPS/G-MOPS PLUS *sold on the market, unless otherwise stated.*

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

G-MOPS: General equipment and sterile non-toxic disposables for the IVF lab including warming incubator, heated stage, warming block, HSA-solution, G-IVF PLUS, Hyase-10X, OVOIL, ICSI, G-1 PLUS, G-2 PLUS and G-TL.

G-MOPS PLUS: General equipment and sterile non-toxic disposables for the IVF lab including warming incubator, heated stage, warming block, Hyase-10X, OVOIL, ICSI, G-1 PLUS, G-2 PLUS and G-TL.

4 Risks and warnings

4.1 Residual risks and undesirable effects

For G-MOPS, all the risks were acceptable after risk control measures. For G-MOPS PLUS, there are two residual risks that remain unacceptable after risk control measures. These risks have the hazardous situations ‘viral infection of the patient’ or ‘viral infection of user’ and are related to HSA present in the device. HSA is derived from human blood and could theoretically be a vector for various diseases such as hepatitis B (HBs-Ag), hepatitis C (Anti-HSV) and HIV 1/2 (Anti-HIV 1/2). The probability of patient or user being virally infected during IVF treatment is extremely small, yet the risk is considered unacceptable. Systematic literature search conducted during clinical evaluation has not identified any negative effects or infection associated with the use of HSA in IVF media. No undesirable effect of adverse event has been reported for any of the Vitrolife’s media containing HSA. The benefit-risk evaluation performed during risk analysis has concluded that the benefits of using HSA in IVF media are greater than the risks associated with blood-borne contamination as Vitrolife applies relevant safety measures. The raw material source of HSA used in Vitrolife’s media have been tested for blood-borne diseases by accredited laboratories.

Risks related to G-MOPS with an effect on patient or end user.

Effect	Hazardous situation
Patient	• Patient exposed to gentamicin • Patient exposed to lipoic acid • Patient exposed to non-biocompatible product • Patient exposed to high level of endotoxins • Patient exposed to microbial contamination or contaminated media • Patient exposed to contaminated media or high level of endotoxins • Patient exposed to unintended product • Allergic patient exposed to gentamicin

Effect	Hazardous situation
End user	• User exposed to gentamicin • User exposed to lipoic acid • Allergic user exposed to gentamicin

Risks related to G-MOPS PLUS with an effect on patient or end user

Effect	Hazardous situation
Patient	• Patient exposed to non-biocompatible product • Patient exposed to microbial contamination or contaminated media • Patient exposed to contaminated HSA • Allergic patient exposed to gentamicin
End user	• User exposed to gentamicin • User exposed to HSA • User exposed to lipoic acid • User exposed to contaminated HSA • Allergic user exposed to gentamicin

No adverse events or undesirable side-effects have been reported for the device during its time on the market. To control risks, raw materials for G-MOPS/G-MOPS PLUS were quality tested and each LOT of the final product is tested for pH, osmolality, sterility, bacterial endotoxins and embryo toxicity. Additionally, the user is informed about the device components, contraindication, and precautions by providing information on labels and the Instruction for Use.

4.2 Warnings and precautions

Contraindications for G-MOPS

G-MOPS contains gentamicin. Do not use in patients with known hypersensitivity/allergy to the component.

Precautions related to the use of G-MOPS

- Discard product if bottle integrity is compromised. Do not use G-MOPS if it appears cloudy.
- To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique.
- The risk 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 and the competent authority of the Member State in which the user and/or patient is established.
- Not to be used as an injectable product other than follicle flushing during oocyte retrieval.
- Discard the product according to standard clinical practice for medical hazardous waste when the procedure is finished.

Contraindications for G-MOPS PLUS

G-MOPS PLUS contains gentamicin. Do not use in patients with known hypersensitivity/allergy to the component.

Precautions related to the use of G-MOPS PLUS

- Discard product if bottle integrity is compromised. Do not use G-MOPS PLUS if it appears cloudy.
- G-MOPS PLUS contains human serum albumin.
- Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBc, HCV, and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.
- To avoid contamination Vitrolife strongly recommends that media should be opened and used only with aseptic technique.
- The risk 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 and the competent authority of the Member State in which the user and/or patient is established.
- Not for injection.

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 G-MOPS/G-MOPS PLUS 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

There is no clinical investigation conducted for G-MOPS and G-MOPS PLUS before their CE-marking.

5.3 Summary of clinical data from other sources, if applicable

Clinical experience data from multi-center evaluation comparing Vitrolife’s G5 Series media (include G-MOPS supplemented with HSA; identical to G-MOPS PLUS) and GIII Series media (includes G-MOPS/G-MOPS PLUS version 3 media) were collected previously (Vitrolife’s internal data). The evaluation had two parts: sibling study and a main study. Data were collected from clinics validating and comparing G5 Series with the previous version (GIII Series), with totally 1345 patients included (100 in sibling study, 1245 in main study). The devices in the two groups were used according to their Indications for Use.

Results from the Multi Center Evaluation of Vitrolife Media - G5 Series™ versus GIII Series™ (Vitrolife, data on file).

	Endpoint/ parameter examined	Results, G-MOPS included (G5 Series) *	Results, G-MOPS/G-MOPS PLUS included (GIII Series)	p-value
Sibling study	Fertilization rate, IVF	64%	68%	NS
	Fertilization rate, ICSI	72%	70%	NS
	Clinical pregnancy rate	53%	40%	NS
	Implantation rate	40%	45%	NS
Main study	Fertilization rate, IVF	69%	58%	0.001
	Fertilization rate, ICSI	76%	75%	NS
	Blastocyst development	48%	42%	NS
	Clinical pregnancy rate	47%	50%	NS
	Implantation rate	27%	30%	NS

Abbreviations: NS, not significant

**Note: G-MOPS/G-MOPS PLUS in the G5 Series is identical to current G-MOPS/G-MOPS PLUS available on the market*

The above data include the use of G-MOPS supplemented with HSA- solution in the G5 Series group. The only difference between G-MOPS and G-MOPS PLUS is related to HSA supplementation and G-MOPS supplemented with HSA-solution is identical to G-MOPS PLUS. In the sibling study, no significant differences were observed between the two media groups. In the main study, there were significantly more oocytes fertilized with conventional IVF in the G5 group as compared to the GIII group. Results on blastocyst development, clinical pregnancy and implantation showed no significant differences between G5 and GIII Series of Vitrolife's IVF media.

A systematic literature search has identified several publications reporting fertilization rates from treatment cycles including the use of G-MOPS/G-MOPS PLUS for handling and manipulation of oocytes at ambient atmosphere (Guo *et al*., 2021; Jin *et a*l., 2021, Liu *et al*., 2021; Radwan *et al*., 2021; Ten *et al*., 2021; Zhou *et al*., 2021; Jiang *et al*., 2022; Kadoura *et al*., 2022; Li *et al*., 2022; Tao *et al*., 2022; Esmaeilian *et al*., 2023). Based on the Indication for Use, the relevant endpoint to determine safety and performance of G-MOPS/G-MOPS PLUS after handling and manipulation of oocytes is fertilization rate and the data obtained from scientific literature were compared to the recommended competency values described in the Vienna consensus meeting report on the ART laboratory performance indicators (ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine, 2017).

G-MOPS can be used for oocyte collection and the studies by (Jannatifar et al. 2022; Jiang et al. 2022; Jia et al. 2023) reporting results after the use of G-MOPS for oocyte collection (follicle flushing) confirms its safe use. According to the Indications for Use, G-MOPS/G-MOPS PLUS can be used during handling and manipulation of embryos at ambient atmosphere. The studies (Hao et al. 2022; Idarraga et al. 2022; Liu et al. 2022; Dong et al. 2023) reported the use of G-MOPS/G-MOPS PLUS during blastocyst biopsies and the outcomes support their safe use for embryo handling/manipulation. Several studies have reported clinical pregnancy, live births and/or postnatal results (Aslan Öztürk et al. 2022; Greco et al. 2022; Hao et al. 2022; Jannatifar et al. 2022; Jiang et al. 2022; Ombelet et al. 2022; Tao et al. 2022; van Duijn et al. 2022; Zafardoust et al. 2022; Dong et al. 2023; Handayani et al. 2023; Jiang et al. 2023; Lara-Cerrillo et al. 2023; Le et al. 2023; Prasetiawati et al. 2023; Salehpour et al. 2023; Wang et al. 2023) with a total of 4308 children born from treatment cycles including the use of G-MOPS/G-MOPS PLUS. There is no recommended competency value for clinical pregnancy and the

yearly European results published by European Society of Human Reproduction and Embryology (ESHRE) is used as a reference.

As part of PMS, Vitrolife has collected feedback on the use of G-MOPS from different clinics. An IVF center in Turkey has confirmed that they used G-MOPS for oocyte collection procedure until January 2020 and that the device performed according to its Indication for Use. Additionally, feedbacks were collected from two clinics in UK which confirmed the safe use of G-MOPS for oocyte collection procedure and G-MOPS PLUS for embryo handling and manipulation.

No undesirable side-effect, trends or vigilance reports have been identified for G-MOPS/G-MOPS PLUS during their post-market surveillance (PMS). Data from biological evaluation concluded biological safety and biocompatibility of the devices.

5.4 An overall summary of the clinical performance and safety

According to the Indication for Use, the clinical benefit of Gx-MOPS PLUS is to support handling and manipulation of oocytes and embryos in ambient atmosphere, which is supported by data from published scientific literature. The fertilization rates reported after use of Gx-MOPS PLUS (Ueno et al. 2021) align with the ESHRE competency value (ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine 2017).The CPRs reported after use of Gx-MOPS PLUS (Ueno et al. 2021) align with the yearly European results published by ESHRE (Smeenk et al. 2023). Data from post-market surveillance (PMS) and risk management also support the safety and performance of Gx-MOPS PLUS. There are no indications of any negative effects from use of Gx-MOPS PLUS. The risks associated with the use of the device are considered acceptable when weighed against the benefits. Therefore, the benefit-risk profile is considered to be acceptable according to 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 G-MOPS/G-MOPS PLUS. However, general PMCF procedures, such as screening of scientific literature and searching adverse event databases and conducting a PMCF end user survey will be performed.

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. There are no therapeutic alternatives for patients at this stage.

Fertility preservation can be considered as a therapeutic alternative for patients undergoing ART. It serves as a proactive approach to safeguard reproductive potential, especially when medical conditions or treatments may impact fertility.

G-MOPS and G-MOPS PLUS are media intended for use in ART for oocyte collection (G-MOPS) and handling and manipulation of oocytes and embryos in ambient atmosphere (G-MOPS/G-MOPS PLUS). Devices with similar intended uses as Gx-MOPS PLUS are available in the European Union or other international markets.

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 G-MOPS/G-MOPS PLUS. As no special design feature or safety concerns were identified for G-MOPS/G-MOPS PLUS, there is no specific training required for the end-users.

8 Reference to any harmonized standards and common specifications applied

- Medical Devices Regulation (EU) 2017/745 (MDR)
- EN ISO 13485:2016. Medical devices — Quality management systems — Requirements for regulatory purposes
- EN ISO 14971:2019. Medical devices — Application of risk management to medical devices
- EN ISO 15223-1:2016. Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
- EN ISO 20417:2021. Medical devices — Information to be supplied by the manufacturer MEDDEV 2.7/4
- EN ISO/TR 20416:2020. Medical devices — Post-market surveillance for manufacturers
- 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 will be performed according to the procedure outlined in Annex IX of the MDR (EU) 2017/745.

9 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1	2021/04/25	Initial version of draft SSCP for G-MOPS/G-MOPS PLUS (REP-2367-v.1.0)	
2	2022/06/07	Annual update of SCCP for G-MOPS/G-MOPS PLUS (REP-2367-v.2.0)	
3	2023/05/04	Annual update of SSCP for G-MOPS/G-MOPS PLUS (REP-2367-v.3.0)	
4	2025/01/02	Annual update of SSCP for G-MOPS/G-MOPS PLUS (REP-2367-v.4.0)	
5	2025/03/10	Edit section 6 of SSCP for G-MOPS/G-MOPS PLUS (REP-2367-v.5.0)	☑ Yes Validation language: English

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