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Summary of safety and clinical performance: RapidVit™ Omni/RapidWarm™ Omni

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	RapidVit Omni/RapidWarm Omni
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	RapidVit Omni: 735002591AAYES RapidWarm Omni: 735002591AAZEU
1.5	Global Medical Device Nomenclature (GMDN) code	42850
1.6	Class of device	Class III
1.7	Year when the first certificate (CE) was issued covering the device	2016
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

RapidVit Omni/RapidWarm Omni are medical devices intended for use in assisted reproductive technology (ART) as media for vitrification of oocytes through to blastocyst stage embryos and warming of vitrified oocytes through to blastocyst stage embryos, respectively.

2.2 Indication and target population

RapidVit Omni: Media for vitrification of oocytes through to blastocyst stage embryos.

RapidWarm Omni: Media for warming of vitrified oocytes through to blastocyst stage embryos.

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The target patient population is an adult or reproductive-age population that undergoes *in vitro* fertilization (IVF) treatment or fertility preservation.

2.3 Contraindications and/or limitations

RapidVit Omni/RapidWarm Omni contain gentamicin. Do not use in patients with known hypersensitivity/allergy to the component. (However, according to the Indications for Use, RapidVit Omni/RapidWarm Omni do not have patient contact.)

3 Device description

3.1 Description of the device

RapidVit Omni and RapidWarm Omni are MOPS buffered media intended to support vitrification and warming of oocytes through to blastocyst stage embryos, respectively. Based on their Indications for Use, RapidVit Omni and RapidWarm Omni will have contact with oocytes and embryos.

The devices are sterile filtered using aseptic technique. RapidVit Omni and RapidWarm Omni are stable until the expiry date shown on the bottle labels and the LOT specific Certificate of Analysis. Media bottles can be used for up to two weeks after first opening, use aseptic technique and minimize the time outside the refrigerator. Record opening date on the bottle. Discard excess media no later than two weeks after first opening. Based on regulatory guidelines, the medicinal components present in RapidVit Omni and RapidWarm Omni are gentamicin and human serum albumin (HSA). Gentamicin, an antibiotic, may cause sensitization or allergic reactions in the patient or user.



Figure 1. RapidVit Omni/RapidWarm Omni

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

There have been no previous versions of RapidVit Omni/RapidWarm Omni on the market.

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

Not applicable.

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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 heating stage, CO_2 incubator, culture media, storage device and storage system.

4 Risks and warnings

4.1 Residual risks and undesirable effects

After mitigation, there are two unacceptable residual risks due to the presence of HSA, with the hazardous situations “Patient exposed to contaminated human serum albumin (HSA)” and “User exposed to contaminated human serum albumin (HSA)”. However, according to the Indications for Use, RapidVit Omni/RapidWarm Omni do not have contact with the patient. The end user (IVF professional) is expected to follow the ESHRE revised guidelines for good practice in IVF laboratories and use the devices according to their IFUs. The benefit-risk analysis of these risks concluded that the benefits of including HSA in RapidVit Omni/RapidWarm Omni outweigh the risks associated with blood-borne contamination. No case reports of allergic/hypersensitivity reactions or infections associated with HSA during ART procedures have been reported. No adverse events or undesirable side-effects have been reported for the devices during their time on the market. To mitigate risks, raw materials for RapidVit Omni/RapidWarm Omni are quality tested, and each LOT of the final product is tested for pH, osmolality, sterility, embryo toxicity and bacterial endotoxins. Additionally, the user is informed about the device components, contraindications and precautions by providing information on labels and the IFUs.

All the clinical risks that could occur during the use of RapidVit Omni/RapidWarm Omni are presented below.

Effect	Hazardous situation
Patient	Patient exposed to contaminated human serum albumin (HSA)*
End user	Allergic user exposed to gentamicin
	User exposed to gentamicin
	User exposed to human serum albumin (HSA)
	User exposed to contaminated human serum albumin (HSA)*

*Unacceptable residual risks. All other clinical risks are acceptable after risk control measures.

4.2 Warnings and precautions

Precautions related to the use of RapidVit Omni are listed.

- The long-term safety of vitrification and/or blastocyst collapse on children born following this method of oocyte or embryo cryopreservation procedure has not been established.
- The risk of reproductive toxicity and developmental toxicity for IVF media, including Vitrolife’s IVF media, have not been determined and are uncertain.
- Discard product if bottle integrity is compromised. Do not use RapidVit Omni if it appears cloudy.
- RapidVit Omni 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

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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.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer.
- Not for injection.
- Discard the product according to standard clinical practice for medical hazardous waste when the procedure is finished.

Precautions related to the use of RapidWarm Omni are listed.

- The long-term safety of vitrification and/or blastocyst collapse on children born following this method of oocyte or embryo cryopreservation procedure has not been established.
- The risk of reproductive toxicity and developmental toxicity for IVF media, including Vitrolife's IVF media, have not been determined and are uncertain.
- Discard product if bottle integrity is compromised. Do not use RapidWarm Omni if it appears cloudy.
- RapidWarm Omni 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.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer.
- Not for injection.
- Discard the product according to standard clinical practice for medical hazardous waste when the procedure is finished.

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 RapidVit Omni/RapidWarm Omni during their lifecycles.

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

No pre-market clinical investigations were performed.

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5.3 Summary of clinical data from other sources, if applicable

A systematic literature search was conducted to identify clinical data on the safety and performance of RapidVit Omni/RapidWarm Omni. Post-warming survival rates reported after use of RapidVit Omni/RapidWarm Omni [1-9] align with the Alpha and ESHRE competency values [10, 11]. Clinical pregnancy rates (CPRs) reported after use of RapidVit Omni/RapidWarm Omni [3, 4, 6-8, 12-16] generally align with the European results published by ESHRE [17]. Several studies reported data on live births after the use of RapidVit Omni/RapidWarm Omni [3, 7, 13-15, 18, 19], which supports the safety of the devices. According to the results from the literature search, no deviation was found in the safety or performance of the devices. No post-market clinical follow-up (PMCF) studies have been conducted for RapidVit Omni/RapidWarm Omni. However, results from a PMCF end user survey confirm the safety and performance of RapidVit Omni/RapidWarm Omni and ensure the continued acceptability of the benefit-risk ratio. No emerging risks or unknown side-effects were identified, and no known side-effects and/or contraindications were found. RapidVit Omni/RapidWarm Omni have been on the market since 2016, and no non-serious incidents or undesirable side-effects have been identified after their use with a frequency or severity that negatively impact their benefit-risk profile.

5.4 An overall summary of the clinical performance and safety

According to the Indications for Use, the clinical benefit of RapidVit Omni/RapidWarm Omni is as media to support for vitrification of oocytes through to blastocyst stage embryos and warming of oocytes through to blastocyst stage embryos, respectively.

Post-warming survival rates reported after use of RapidVit Omni/RapidWarm Omni [1-9] align with the Alpha and ESHRE competency values [10, 11]. CPRs reported after use of RapidVit Omni/RapidWarm Omni [3, 4, 6-8, 12-16] generally align with the European results published by ESHRE [17]. Several studies reported data on live births after the use of RapidVit Omni/RapidWarm Omni [3, 7, 13-15, 18, 19], which supports the safety of the devices. Data from post-market surveillance, including a PMCF end user survey, and risk management also support the safety and performance of RapidVit Omni/RapidWarm Omni. There are no indications of any negative effects from use of RapidVit Omni/RapidWarm Omni. As identified in the risk management documents, two residual risks due to the presence of HSA are unacceptable. However, after benefit-risk evaluation, the benefits of using HSA in the devices outweigh the risks associated with blood-borne contamination. All other risks are acceptable after risk control measures. According to the results of the literature search, the risk of an allergic/hypersensitivity reaction (or infection) associated with HSA, gentamicin or antibiotics when used for ART procedures is low. No new risks have been identified or are expected when the devices are used according to their Indications for Use. Therefore, the benefit-risk profile is 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 RapidVit Omni/RapidWarm Omni. However, general PMCF procedures, such as screening scientific literature, searching adverse event databases and performing a PMCF end user survey will be performed.

6 Possible diagnostic or therapeutic alternatives

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

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Fertility preservation can serve as a therapeutic alternative for patients undergoing ART, offering a proactive measure to safeguard reproductive potential, particularly in cases where medical conditions or treatments may impact fertility.

Cryopreservation methods include slow freezing and vitrification. Current evidence indicates that vitrification is superior to slow freezing in terms of cryosurvival rates and clinical outcomes for oocytes, cleavage-stage embryos and blastocysts. Devices with similar intended uses as RapidVit Omni/RapidWarm Omni 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 the ART field and use the devices according to their IFUs. As no special design feature or safety concerns were identified for RapidVit Omni/ RapidWarm Omni, no specific training is required for 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
- ISO/TR 20416:2020. Medical devices — Post-market surveillance for manufacturers
- EN ISO 20417:2021. Medical devices — Information to be supplied by the manufacturer
- MEDDEV 2.7/1 revision 4. Clinical evaluation – A guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC. June 2016
- 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	2021-03-26	Initial version of SSCP for RapidVit Omni/RapidWarm Omni (REP-3366-v.1.0)	
2	2021-08-16	Annual update of SSCP for RapidVit Omni/RapidWarm Omni (REP-3366-v.2.0)	
3	2022-05-16	Annual update of SSCP for RapidVit Omni/RapidWarm Omni (REP-3366-v.3.0)	

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SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
4	2022-10-14	Address DNV clinical NCs (REP-3366-v.4.0)	☑ Yes Validation language: English
5	2023/06/28	Annual update of SSCP for RapidVit Omni/RapidWarm Omni (REP-3366-v.5.0)	
6	2023/08/22	Correction of page header of v.5.0, no change in document content. (REP-3366-v.6.0)	
7	2024/05/15	Annual update of SSCP for RapidVit Omni/RapidWarm Omni (REP-3365-v.7.0)	
8	2025/04/10	Edit Section 6 of SSCP for RapidVit Omni/RapidWarm Omni (REP-3365-v.8.0)	☑ Yes Validation language: English
9	See publish date	Annual update of SSCP for RapidVit Omni/RapidWarm Omni (REP-3365-v.9.0)	☑ Yes Validation language: English

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