Summary of Safety and Clinical Performance
SpermWash®/SpermTec® Wash

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 the intended users.

1 Device identification and general information

1.1 Device trade name(s)

SpermWash®
SpermTec® Wash

1.2 Manufacturer's name and address

FertiPro NV
Industriepark Noord 32
8730 Beernem
Belgium

Exclusive distributor:
Gynotec B.V.
Rijksweg 150
6581 ET Malden
The Netherlands

1.3 Manufacturer's single registration number (SRN)

BE-MF-000000313

1.4 Basic UDI-DI

5411967GYNW6V

1.5 Medical device nomenclature description/text

Applicable EMDN code: U08020502 (Materials/solutions for preparation/handling for assisted reproduction)

1.6 Class of device

Europe: Class III devices according to Annex VIII of the MDR (Regulation (EU) 2017/745)

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

- CE-marking according to the Council Directive 93/42/EEC: 2012
- CE-marking according to Regulation (EU) 2017/745: 13/11/2023

1.8 Authorized representative if applicable; name and the SRN

Not applicable

1.9 NB's name and single identification number

BSI Group The Netherlands BV
NB identification number: 2797

2 Intended use of the device

2.1 Intended use

SpermWash® / SpermTec® Wash are intended for in vitro procedures including washing of human gametes (sperm and oocytes), sperm swim-up procedures, intra-uterine insemination (IUI) of the spermatozoa and intracytoplasmic sperm injection (ICSI). SpermWash® / SpermTec® Wash can also be used for human embryo washing and holding, and for embryo transfer in the uterine cavity.

2.2 Indication(s) and intended patient groups

- **Indications for use:** For use during ART procedures of patients and couples undergoing infertility treatments.
- **Intended users:** The intended users are ART professionals (lab technicians, embryologists, or medical doctors).
- **Target patient populations**: The target patient population consists of patients and couples undergoing infertility treatments.

2.3 Contraindications and/or limitations

There are no known contra-indications/ limitations for SpermWash® / SpermTec® Wash.

3 Device description

3.1 Description of the device

- For the principle of operation, reference is made to the IFU: FP09 I08_SW R01 (SpermWash®) and FP09 I08_STW R01 (SpermTec® Wash)
- SpermWash® / SpermTec® Wash are not intended for single use. Multiple single-procedures can be performed with one bottle of SpermWash® / SpermTec® Wash. The media can be used up to 7 days after bottle opening (when sterile conditions are maintained and the products are stored at 2-8°C).
- SpermWash® / SpermTec® Wash are sterilized using aseptic processing techniques (filtration).
- SpermWash® / SpermTec® Wash contain HEPES and are designed to enable *in vitro* manipulation of gametes and embryos outside the CO_2 incubator. The media consist of a balanced salt solution supplemented with carbohydrate energy sources such as glucose, pyruvate and lactate. The media contain phenol red, human serum albumin (HAS) and gentamicin:
    - The inclusion of HSA (which is a medicinal substance derived from human blood plasma) in ART media from FertiPro is approved by the EMA (European Medicine Agency).
    - The added gentamicin is European Directorate for the Quality of Medicines and HealthCare (EDQM) and is approved by the MEB (Medicines Evaluation Board, the competent authority of The Netherlands).
- Direct physical contact occurs between the media products and human gametes or embryos. With embryo transfer and IUI, the media come into direct contact with the uterus mucosal membranes of the patient.

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

No previous generation of the devices have been brought on the market by FertiPro.

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

Not applicable, no accessories identified.

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

SpermWash® / SpermTec® Wash are to be used with general ART labware and/or media.

4 Risks and warnings

4.1 Residual risks and undesirable effects

The output from the clinical evaluation report and of the clinical evaluation outcome report of HSA and gentamicin are taken into account in the risk management file of SpermWash® / SpermTec® Wash in order to determine the benefits/risk ratio.

The only remaining residual risk is the inclusion of HSA in SpermWash® / SpermTec® Wash. The inclusion of this medicinal substance derived from human blood plasma in the devices is approved by the EMA.

The major benefit of HSA in SpermWash® / SpermTec® Wash is:

- pH regulator
- Osmotic regulator
- Stabilizator of cell membrane
- Nutrient and carrier of growth promoting substances (i.e. amino acids, vitamins, fatty acids, hormones, growth factors)
- Scavenger (of for example toxins and waste products from cell metabolism)
- Surfactant (anti-adhesion), thereby facilitating gamete and embryo manipulation

A potential risk associated with HSA is the transmission of viral or prion-carried diseases and the batch-to batch variation:

- **Batch-to-batch variation** is still a problem because of the inherent variability in donor blood. Due to this fluctuation, standardization of procedures remains difficult.

  ↔ For this reason, a mouse embryo assay and a human sperm survival assay are routinely performed as part of the batch release criteria

- Secondly; with the use of a human-derived protein source, a potential risk exists of **transmitting viral or prion-carried diseases**.

  ↔ HSA is manufactured with a pasteurization procedure that has led to an excellent viral safety record over the 50 years of clinical use. Only Plasbumin-25 or alternatively, Albunorm 25 will be used as a source of albumin, as these products are covered by a valid Plasma Master File, and the EMA has positively evaluated the usefulness, safety and benefit of the inclusion of these products in FertiPro ART-media.

  ↔ On the other hand, despite the rigorous quality controls, all cell culture media should still be treated as potentially infectious. At present, there is no known test method that can offer full assurance that products derived from human blood will not transmit infectious agents. Direct physical contact occurs between SpermWash® / SpermTec® Wash and human gametes or embryos. With embryo transfer and IUI, the media come

into direct contact with the uterus mucosal membranes of the patient. The instructions for use / MSDS clearly warn that the media contains human albumin solution and that protective clothing should be worn.

Based on the analysis it is concluded that the benefit of adding HSA to the media outweighs the risk and the overall residual risk related to the use of SpermWash® / SpermTec® Wash with inclusion of HSA has been judged acceptable.

With respect to the above, following information is provided to the customer:

- Product composition is clearly indicated on the labels and instructions for use
- Instructions for use contains the following warnings:
  - Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes. Therefore, handle all specimens as if capable of transmitting HIV or hepatitis.
  - All blood products should be treated as potentially infectious. Source material used to manufacture this product was tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore, source material has been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

No other known undesirable side-effects are identified.

4.2 Warnings and precautions

Besides the above, attention should be paid to the following warnings and precautions (as described in the instructions for use):

- Do not use the product if the seal of the container is opened or defect when the product is delivered.
- Do no use if the products shows any evidence of microbial contamination or becomes cloudy.
- Do not use after expiry date.
- Do not freeze before use
- Do not re-sterilize after opening
- Keep in its original packaging until the day of use.
- Gentamicin should not be used on a patient that has a known allergy to gentamicin or similar antibiotics.
- Depending on the number of procedures that will be performed on one day, remove the required volume of medium under aseptic conditions in an appropriate sterile recipient. This is in order to avoid multiple openings/warming cycles of the medium. Discard excess (unused) media.
- Keep away from (sun)light
- Aseptic technique should be used to avoid possible contamination even when the product contains gentamicin
- Always wear protective clothing when handling specimens.

- Any serious incident (as defined in European Medical Device Regulation 2017/745) that has occurred should be reported to FertiPro NV and the competent authority of the Member State in which the user and/or patient is established.

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

Not applicable, no field safety corrective actions with regard to SpermWash® / SpermTec® Wash were needed so far.

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

5.1 Real-word evidence analyses

A literature search is performed to investigate whether embryological and/or clinical ART outcomes obtained during literature search are consistent with the embryological competency limits and/or with the clinical ART outcomes described in two benchmark papers from the ESHRE (see tables below).

The Vienna consensus report published in 2017 is the result of a 2 day consensus meeting of expert professionals from Sweden, Turkey, UK, Australia, Italy, Spain, Belgium, Austria, Ireland, Canada, USA, and Norway. As a starting point for the discussion, two surveys were organized to collect information on indicators used in IVF laboratories worldwide. During the meeting, the results of the surveys, scientific evidence (where available), and personal clinical experience were integrated into presentations by experts on specific topics. After presentation, each proposed indicator was discussed until consensus was reached within the panel (ESHRE Special Interest Group of Embryology, 'The Vienna consensus: report of an expert meeting on the development of art laboratory performance indicators', Hum Reprod Open, 2017: hox011).

The following competency limits concerning embryological outcomes are reported by the expert group:

- ICSI normal fertilization rate: ≥: 55%
- IVF normal fertilization rate: ≥50%
- Blastocyst development rate: ≥30%
- Since multiple factors can have an influence on the embryology outcomes, (ART policy, approach of the clinic, patients characteristics), a value 10% lower than the competency limit is acceptable.

Each year, the ESHRE publishes a peer-reviewed report, which collects, analyses and reports ART data generated in Europe. The most recent report includes data from 1 077 813 treatment cycles (covering the time period from 1 January to 31 December 2019) (Smeenk et al. 2023) and data is summarized in the table below.

ART in Europe, 2020: results generated from European registries by ESHRE.
Smeenk J, Wyns C, De Geyter C, Kupka MS, Bergh C, Cuevas Saiz I, De Neubourg D, Rezabek K, Tandler-Schneider A, Rugescu I, Goossens V. ART in Europe, 2020: results generated from European registries by ESHRE†. Hum Reprod. 2025 Sep 23:deaf179. doi: 10.1093/humrep/deaf179. Epub ahead of print. PMID: 40985526.

In vitro fertilization (IVF):	Intra cytoplasmic sperm injection (ICSI):	Frozen embryo transfer (FET):	Intrauterine insemination (IUI):
Clinical pregnancy rate per aspiration: 6.7 – 36.5%	Clinical pregnancy rate per aspiration: 9.3 – 38.9%	Pregnancy rate per thawing: 21.7 – 52.6%	Delivery rate per cycle (using husband semen IUI-H): 2.7 – 19.0%
Clinical pregnancy rate per transfer:	Clinical pregnancy rate per transfer:	Pregnancy rate per transfer: 22.3 – 54.9%	Delivery rate per cycle (using donor semen IUI-D):

23.3 – 48.8% Delivery rate per aspiration: 4.4 – 28.8% Delivery rate per transfer: 14.9 – 43.9%	25.1 – 49.0% Delivery rate per aspiration: 8.0 – 28.2% Delivery rate per transfer: 10.3 – 39.4%	 Delivery rate per thawing: 4.8 – 43.4% Delivery rate per transfer: 4.9 – 45.2%	8.2 – 20.9%

As there are no alternative treatment options that can be used for gamete/embryo washing/handling and ART procedures, all data included in the ESHRE report are generated using SpermWash® / SpermTec® Wash or a similar device available on the market. Reported outcomes in the benchmark paper can therefore be considered as benchmark data for ART procedures. Nevertheless, when comparing clinical data, one should be aware that:

- During ART processes, gametes/embryos come into contact with several (other) ART media and undergo a lot of manipulations that all can have an influence on the reported outcomes.
- Depending on the patient characteristics, different outcomes can be obtained.

48 articles were retrieved that describe the safety and performance of SpermWash® / SpermTec® Wash. Due to reasons of confidentiality, these papers are not listed. Note however that all outcomes described in these additional articles are consistent with the outcomes as described in the benchmark papers.

It can be concluded from these papers that embryological and/or clinical ART outcomes when SpermWash® / SpermTec® Wash is used for gamete/embryo washing and handling, swim-ups, density gradient preparation, or during IVF, ICSI, IUI are consistent with the embryological competency limits (see above) and/or with the published ART outcomes as reported by the ESHRE (see above) suggesting a safe and adequate performance of SpermWash® / SpermTec® Wash.

5.2 Device registries

In addition, clinical data is obtained from IVF centers worldwide that use the media. ART outcomes of these clinics are consistent with clinical outcomes described in national public registers of the countries in which the IVF centers are located or with the ART outcomes as described in the benchmark paper from the ESHRE (see above). This suggests a safe and adequate performance of SpermWash® / SpermTec® Wash.

5.3 Analysis complaints, customer/market feedback, vigilance

No additional actions were initiated, based on the cumulative nature and/or occurrence of all complaints, customer/market feedback and vigilance (if any) during the PMCF analysis.

5.4 An overall summary of the clinical performance and safety

SpermWash® / SpermTec® Wash functions as stated by the manufacturer.

This is established by clinical data obtained during literature search which demonstrate that embryology and/or ART outcomes of procedures in which SpermWash® / SpermTec® Wash is used, are consistent with the competency limits reported by the Vienna consensus group and/or with the published ART outcomes as reported by the ESHRE (see above). In addition, clinical data from multiple IVF centers in Europe show that ART outcomes of procedures in which SpermWash® / SpermTec® Wash is used, are consistent with published national ART outcomes in the country where the IVF clinic is located or are consistent with the published outcomes as reported by the ESHRE (see above).

Moreover, there is no evidence from the clinical data, as well as from the registered complains, market/customer feedback and/or vigilance that SpermWash® / SpermTec® Wash is toxic for gametes and embryos, nor that the media have no risk for mutagenity, oncogenicity, teratogenity, carcinogenity,

cytotoxicity, allergenicity and irritancy for patients and users. Furthermore, no infrequent complications or problems were detected. No infrequent complications or problems were detected.

5.5 Ongoing or planned post-market surveillance and post-market clinical follow-up

Post-Market Surveillance and Post-market clinical follow-up for SpermWash® / SpermTec® Wash (including PMCF for the HSA and gentamicin component included in SpermWash® / SpermTec® Wash) will be performed at least yearly and will include analyses of real-world evidence by performing literature search, screening of device registers for clinical data, as well as analysis of all complaints, customer/market feedback and vigilance.

This Summary of Safety and Clinical Performance will be updated with information from the post-market surveillance and post-market clinical follow-up, if this is needed to ensure that any clinical and/or safety information described in this document remains correct and complete.

6 Possible diagnostic or therapeutic alternatives

Several devices as SpermWash® / SpermTec® Wash with a similar intended use are available on the European Union or international markets. Besides these, there are no other alternative treatments that can be used in gamete/embryo washing and/or handling and ART procedures.

7 Suggested profile and training for users

SpermWash® / SpermTec® Wash are used in specialized laboratories performing fertilization techniques, including IVF, ICSI and sperm preparation/analysis. The intended users are IVF professionals (lab technicians, embryologists, or medical doctors).

8 Reference to any applicable common specification(s), harmonized standard(s) or applicable guidance document(s)

The following technical standards apply to SpermWash® / SpermTec® Wash:

MDR 2017/745	European Medical Device Regulation 2017/745 of 5 April 2017.
(EN) ISO 13485:2016 (Amd 11:2021)	Medical devices — Quality management systems — Requirements for regulatory purposes.
EN 556-2:2015	Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' –Requirements for aseptically processed medical devices.
(EN) ISO 20417:2021	Medical devices: information supplied by the manufacturer.
(EN) ISO 14971:2019 (Amd 11:2021)	Medical devices – Application of risk management to medical devices.
(EN) ISO 15223-1: 2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
(EN) ISO 17665:2024	Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
ISO 23640:2011/EN ISO 23640:2015	In vitro diagnostic medical devices: Evaluation of stability of in vitro diagnostic reagents (Applicable with exclusion of the following sections: No standard is available for the evaluation of stability of Medical Devices, therefore this standard is used as guideline for the set-up of the stability testing)
(EN) ISO 11737-1:2018, A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
IEC 62366-1:2015 (Amd 1:2020)	Medical devices - Part 1: Application of usability engineering to medical devices.

NBOG BPG 2014-3	Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System
EMA/CHMP/578661/2010	EMA recommendation on the procedural aspects and dossier requirements for the consultation to the EMA by a notified body on an ancillary medicinal substance or an ancillary human blood derivate incorporated in a medical device or active implantable medical device.
ISO 13408-1:2023 /EN ISO 13408-1:2024	Aseptic processing of health care products – Part 1: general requirements.
(EN) ISO 13408-2:2018	Aseptic processing of health care products – Part 2: Filtration.
(EN) ISO 13408-6:2021	Aseptic processing of health care products – Part 6: Isolator systems.
(EN) ISO 14644-1:2015	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration.
(EN) ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods
ISO 10993-1:2018/EN ISO 10993-1:2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing.
ISO 10993-18:2020/Amd 1/2022 / EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process.
Ph. Eur. 0255	European Pharmacopoeia monograph 0255 – Human albumin solution
Ph. Eur. 331	European Pharmacopoeia monograph 331 – Gentamicin sulfate

9 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
A.1	8/11/2022	Initial version	Version A.1 is validated by the Notified Body Validation language: English
A.2	05/06/2023	Update 2023: addition PMCF data	Not submitted for validation, as there were no significant changes that required validation.
A.3	14/06/2024	Update 2024: addition PMCF data	Not submitted for validation, as there were no significant changes that required validation.
A.4	12/06/2025	Update 2025: addition PMCF data	Not submitted for validation, as there were no significant changes that required validation.
A.5	31/10/2025	Update 2025	Not submitted for validation, as there were no significant changes that required validation.
A.6	25/03/2026	Update address exclusive distributor	Not submitted for validation, as there were no significant changes that required validation.
A.7	27/04/2026	Update 2026	Not submitted for validation, as there were no significant changes that required validation.

10 Summary of the safety and clinical performance of the device intended for patients

A summary of the safety and clinical performance of the device intended for patients, is not applicable as the device is for professional use only.