Summary of Safety and Clinical Performance
IVF Basics HTF media

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)

IVF Basics HTF media

- IVF Basics HTF
- IVF Basics HTF 0.4% HSA
- IVF Basics HTF HEPES
- IVF Basics HTF HEPES 0.4% HSA
- IVF Basics SpermTec M

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

5411967IVFB1WA

1.5 Medical device nomenclature description/text

Applicable EMDN codes:

- **IVF Basics HTF/ IVF Basics HTF 0.4% HSA**
  U08020503 - Materials/culture media for assisted reproduction

- **IVF Basics HTF HEPES/ IVF Basics HTF HEPES 0.4% HSA and IVF Basics SpermTec M**
  U08020502 - Materials/solutions for preparation/handling for assisted reproduction

1.6 Class of device

Class III device 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 (MDD): 2020
- CE marking according to Regulation (EU) 2017/745 (MDR): 16/03/2022

1.8 Authorized representative if applicable; name and the SRN

Not applicable

1.9 Notified Body (NB) and the single identification number

BSI Group the Netherlands BV
NB identification number: 2797

2 Intended use of the device

2.1 Intended use

IVF Basics HTF / IVF Basics HTF 0.4% HSA are used for washing and handling of human gametes, and for handling and conditioning of human embryos. The media are used for the following procedures:

- Washing/handling of human ova
- Washing/handling of spermatozoa
- Swim-up of spermatozoa
- Production of density gradient media
- Washing/handling for human embryos
- Intrauterine insemination (IUI), in vitro fertilization (IVF), intra-cytoplasmatic sperm injection (ICSI)
- Embryo culture from day 1 to blastocyst stage
- Embryo transfer

IVF Basics HTF HEPES / IVF Basics HTF HEPES 0.4% HSA are used for washing and handling of human gametes, and for handling and conditioning of human embryos. The media are used for the following procedures:

- Flushing for oocyte collection
- Washing/handling of human ova
- Washing/handling of spermatozoa
- Swim-up of spermatozoa
- Production of density gradient media
- Washing/handling for human embryos
- Intrauterine insemination (IUI), intra-cytoplasmatic sperm injection (ICSI)
- Embryo transfer

IVF Basics SpermTec M is used for all human sperm washing and sperm preparation techniques including swim-up and density gradient centrifugation. It is also be used for Intrauterine insemination (IUI).

2.2 Indication(s) and intended patient group(s)

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

2.3 Contraindications and/or limitations

There are no known contraindications and/or limitations for IVF Basics HTF media.

3 Device description

3.1 Description of the device

- For the principle of operation, reference is made to:
  - **IVF Basics HTF / IVF Basics HTF 0.4% HSA and IVF Basics HTF HEPES / IVF Basics HTF HEPES 0.4% HSA**
    See Instructions for use: FP09 I70/113 R01_HTF
  - **IVF Basics SpermTec M**
    See Instructions for use: FP09 I70 R01_Sperm
- The devices are are not intended for single use. Multiple single-procedures can be performed. 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).
- IVF Basics HTF media are sterilized using aseptic processing techniques (filtration).
- IVF Basics HTF 0.4% / IVF Basics HTF HEPES 0.4% HSA / IVF Basics SpermTec M contain human serum albumin (HSA). The inclusion of HSA (which is a medicinal substance derived from human blood plasma) is approved by the European Medicine Agency (EMA).

- The media contain gentamicin. The added gentamicin (medicinal substance) complies with the European Pharmacopoeia monograph 0331, is certified by the European Directorate for the Quality of Medicines & HealthCare (EDQM) and is approved by the Medicine Evaluation Board (competent authority of the Netherlands).

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

No previous generation of the device has been brought on the market by FertiPro NV.

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

No accessories identified.

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

For IVF Basics HTF and IVF Basics HTF HEPES (media without HSA): as indicated in the instructions for use, it is strongly suggested to supplement the medium with pharmaceutical grade HSA with registered plasma master file before use.

4 Risks and warnings

4.1 Residual risks and undesirable effects

The output from the clinical evaluation reports of IVF Basics HTF media, Human Serum Albumin (HSA) and/or gentamicin are taken into account in the risk assessment report of IVF Basics HTF media in order to determine the benefits/ risk ratio.

The only remaining residual risk is the inclusion of HSA in IVF Basics HTF media (except for the variants without human albumin). The inclusion of this medicinal substance derived from human blood plasma in the devices is approved by the EMA .

The benefit of adding HSA in IVF Basics HTF media is clear:

- 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 is routinely performed as part of the batch release criteria of the HSA (incoming inspection). A mouse embryo assay and human sperm survival assay are routinely performed as part of the IVF Basics HTF media batch release criteria.
- Transmission of 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 Albunorm 25 are used as a source of albumin, since 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 IVF Basics HTF media.
    - However, 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 IVF Basics HTF media and human gametes or embryos. With embryo transfer and IUI, the media come into direct contact with the uterus mucosal membranes of the patient. With follicle flushing, the media come into

direct contact with ovarian follicles.
- The instructions for use/MSDS clearly warn that the media contain human albumin solution and that protective clothing should be worn.

Based on analysis it is concluded that the benefit of adding HSA to IVF Basics HTF media outweighs the risk, and the overall residual risk related to the use of IVF Basics HTF media with inclusion of HSA has been judged acceptable.

Furthermore, following information is provided on this 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.
  - Handle 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

Attention should be paid to the following additional warnings and precautions (as described in the instructions for use):
- Do not use the product if:
  - seal of the container is opened or defect when the product is delivered
  - it becomes discoloured, shows any evidence of microbial contamination or cloudy
  - expiry date has been exceeded
- Do not freeze before use
- Do not re-sterilize after opening
- Aseptic techniques should be used to avoid possible contamination, even when the products contain gentamicin.
- Always wear protective clothing when working with specimens.
- Any serious incident (as defined in European Medical Device Regulation 2017/745) that has occurred should be reported to FertiPro N.V. and, if applicable, to the competent authority of the EU Member State in which the user and/or patient is established.

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

No field safety corrective actions with regard to IVF Basics HTF media were needed so far.

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

5.1 Real-world evidence analyses

A literature search is performed on a yearly basis, to investigate whether clinical embryology and ART outcomes obtained during the search are consistent with the clinical outcomes described in the following benchmark papers from the European Society of Human Reproduction and Embryology (ESHRE):
- Embryology outcomes:

ESHRE Special Interest Group of Embryology, ESHRE. 2017. **'The Vienna consensus: report of an expert meeting on the development of art laboratory performance indicators'**, Hum Reprod Open, 2017: hox011	ICSI normal fertilization rate:	≥65% (Accepted outcome: 55%)
	IVF normal fertilization rate:	≥60% (Accepted outcome: 50%)

- ART outcomes:

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.	**IVF**	**ICSI**	**Frozen embryo transfer (FET)**	**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%*	**Using husband semen (IUI-H):** Delivery rate per cycle: *2.7 – 19.0%*
	Clinical pregnancy rate per transfer: *23.3 – 48.8%*	Clinical pregnancy rate per transfer: *25.1 – 49.0%*	Pregnancy rate per transfer: *22.3 – 54.9%*	
	Delivery rate per aspiration: *4.4 – 28.8%*	Delivery rate per aspiration: *8.0 – 28.2%*	Delivery rate per thawing: *4.9 – 45.2%*	**Using donor semen (IUI-D):** Delivery rate per cycle: *8.2 – 20.9%*
	Delivery rate per transfer: *14.9 – 43.9%*	Delivery rate per transfer: *10.3 – 39.4%*	Delivery rate per transfer: *8.4 – 42.4%*	

An overview of the articles in literature studying the performance of IVF Basics HTF media is listed in the table below. Overall, it can be concluded from these papers that embryological and ART outcomes when IVF Basics HTF media are used are consistent with the outcomes described in the benchmark papers.

Selected articles describing the use of IVF Basics HTF media in sperm processing:		
(van Rijswijk et al. 2017)	(Hessel et al. 2015)	(Punjabi et al. 2018)
(Lemmens et al. 2016)	(van der Houwen et al. 2014)	(Punjabi et al. 2021)
(Punjabi 2022)	(Sugihara 2023)	(Sugihara et al. 2023)
Selected articles describing the use of IVF Basics HTF media in oocyte/embryo handling:		
(Kleijkers et al. 2016)	(Vergouw et al. 2011)	(Wathlet et al. 2011)
(Vergouw et al. 2008)	(De Vos et al. 2008)	(Mackens et al. 2020)
(Decleer et al. 2020)	(Adriaenssens et al. 2019)	

5.2 Device registries

In addition to the above, ART outcomes of eight IVF clinics located in The Netherlands are included in the clinical evaluation report of IVF Basics HTF media. The ART outcomes of these clinics are consistent with the national ART outcomes of The Netherlands This suggests a safe and adequate performance of IVF Basics HTF media.

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

Overall, it can be concluded that IVF Basics HTF media function as stated by the manufacturer[1].

This is established by clinical data obtained during literature search which demonstrate that embryological and clinical ART outcomes, when IVF Basics HTF media were used, fall within the range of the outcomes described in the benchmark papers. In addition, clinical ART outcomes from IVF centers that use IVF Basics HTF media are consistent with the national ART outcomes. Moreover, there is no evidence from the clinical data, as well as from the registered complains, market/customer feedback and/or vigilance that IVF Basics HTF media is toxic for gametes and embryos, nor that the media have

[1] Note that limited data is available on the clinical use of IVF Basics SpermTec M. Therefore, clinical safety and performance of IVF Basics SpermTec M was also based on equivalence to IVF Basics HTF HEPES (HSA).

risk for mutagenity, oncogenicity, teratogenity, carcinogenity, cytotoxicity, material-mediated pyrogenicity, allergenicity and irritancy for patients and users.

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

PMS/PMCF for IVF Basics HTF media (including PMS/PMCF for the HSA and gentamicin component included in IVF Basics HTF media) will be performed at least yearly and will include analyses of real-world evidence by performing a literature search, screening of device registers for clinical data, as well as analysis of all complaints, customer/market feedback, vigilance.

This SSCP will be updated with information from the PMS/PMCF, 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

Media with similar intended use as IVF Basics HTF media are available on the European Union or international markets. Besides these media, there are no other alternative treatments that can be used.

7 Suggested profile and training for users

IVF Basics HTF media are used by ART professionals (lab technicians, embryologists, or medical doctors).

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

The following technical standards apply to IVF Basics HTF media:

ISO 13485:2016/ EN ISO 13485:2016 (Amd 11:2021)	Medical devices — Quality management systems — Requirements for regulatory purposes.
MDR 2017/745	European Medical Device Regulation 2017/745 of 5 April 2017.
EN 556-2:2024	Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' –Requirements for aseptically processed medical devices.
(EN) ISO 20417:2021	Information to be supplied by the manufacturer.
ISO 14971:2019/ 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 17665-1:2024	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 rev.1	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.
(EN) ISO 10993-3:2014	Biological evaluation of medical devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.

(EN) ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity.
ISO 10993-9:2019 EN ISO 10993-9:2021	Biological evaluation of medical devices -- Part 9: Framework for identification and quantification of potential degradation products.
ISO 10993-10:2021 EN ISO 10993-10:2023	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization.
ISO 10993-11:2017 EN ISO 10993-11:2018	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity.
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.
(EN) ISO 10993-23:2021	Biological evaluation of medical devices – Part 23: Tests for irritation.
(EN) ISO 22442-1: 2020	Medical devices utilizing animal tissues and their derivatives: Part 1: Application of risk management
Ph. Eur. 331	European Pharmacopoeia monograph 331 – Gentamicin sulfate
Ph. Eur. 0255	European Pharmacopoeia monograph 0255 – Human albumin solution

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

Not applicable, since IVF Basics HTF media are for professional use only.

10 Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
A.3	01/09/2021	Initial validated version	• Version A.3 is validated by the Notified Body • Validation language: English
A.4	26/01/2022	Update 2022	Not submitted for validation, as there were no significant changes that required validation.
A.5	07/03/2023	Update 2023	Not submitted for validation, as there were no significant changes that required validation.
B.1	08/11/2023	Name change to IVF Basics HTF media (CC220322-03)	• Version B.1 is validated by the Notified Body • Validation language: English
B.2	22/02/2024	Update 2024	Not submitted for validation, as there were no significant changes that required validation.
B.3	16/03/2025	Update 2025	Not submitted for validation, as there were no significant changes that required validation.
B.4	06/02/2026	Update 2026	Not submitted for validation, as there were no significant changes that required validation.
B.5	25/03/2026	Update address exclusive distributor	Not submitted for validation, as there were no significant changes that required validation.

11 References

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