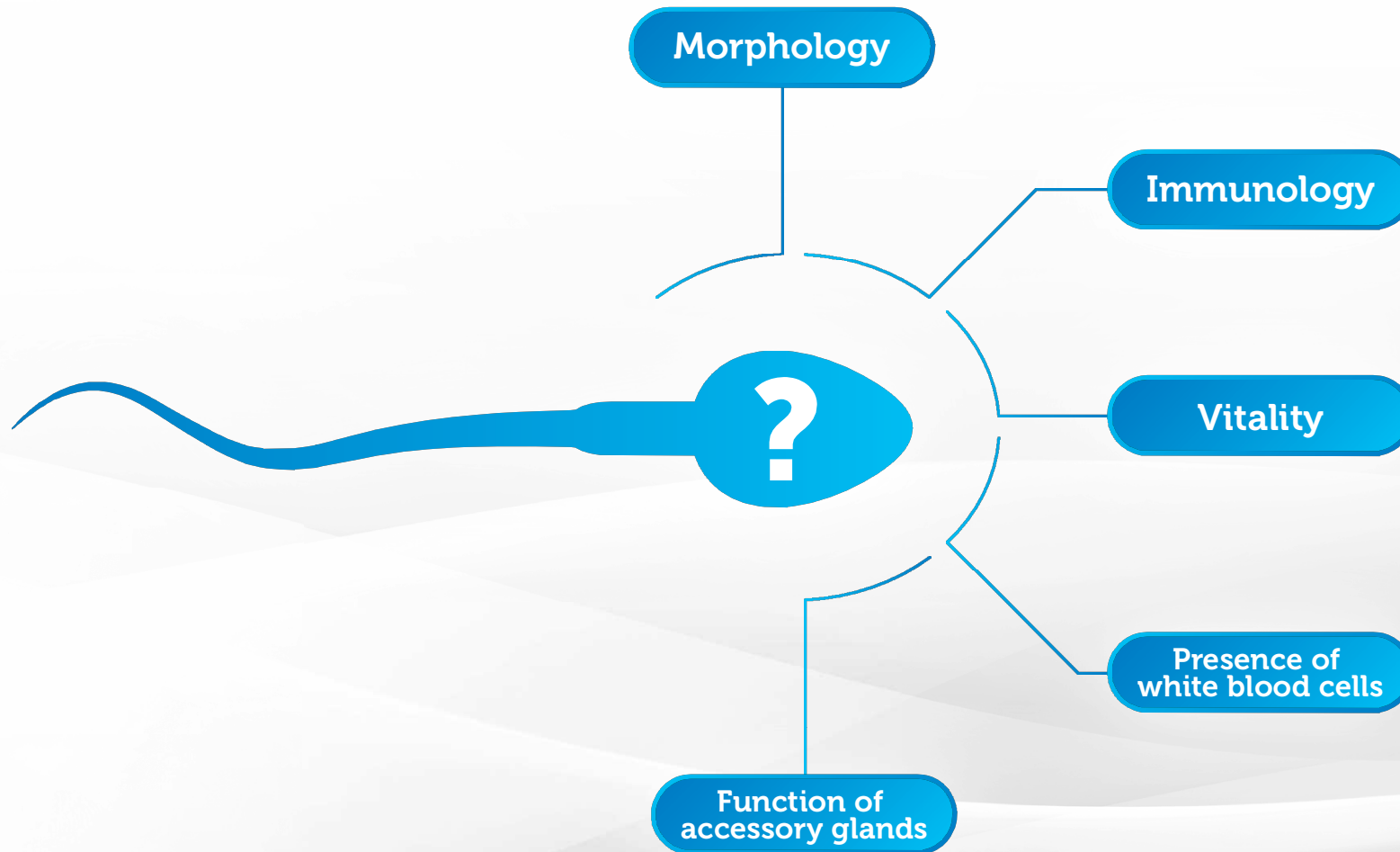
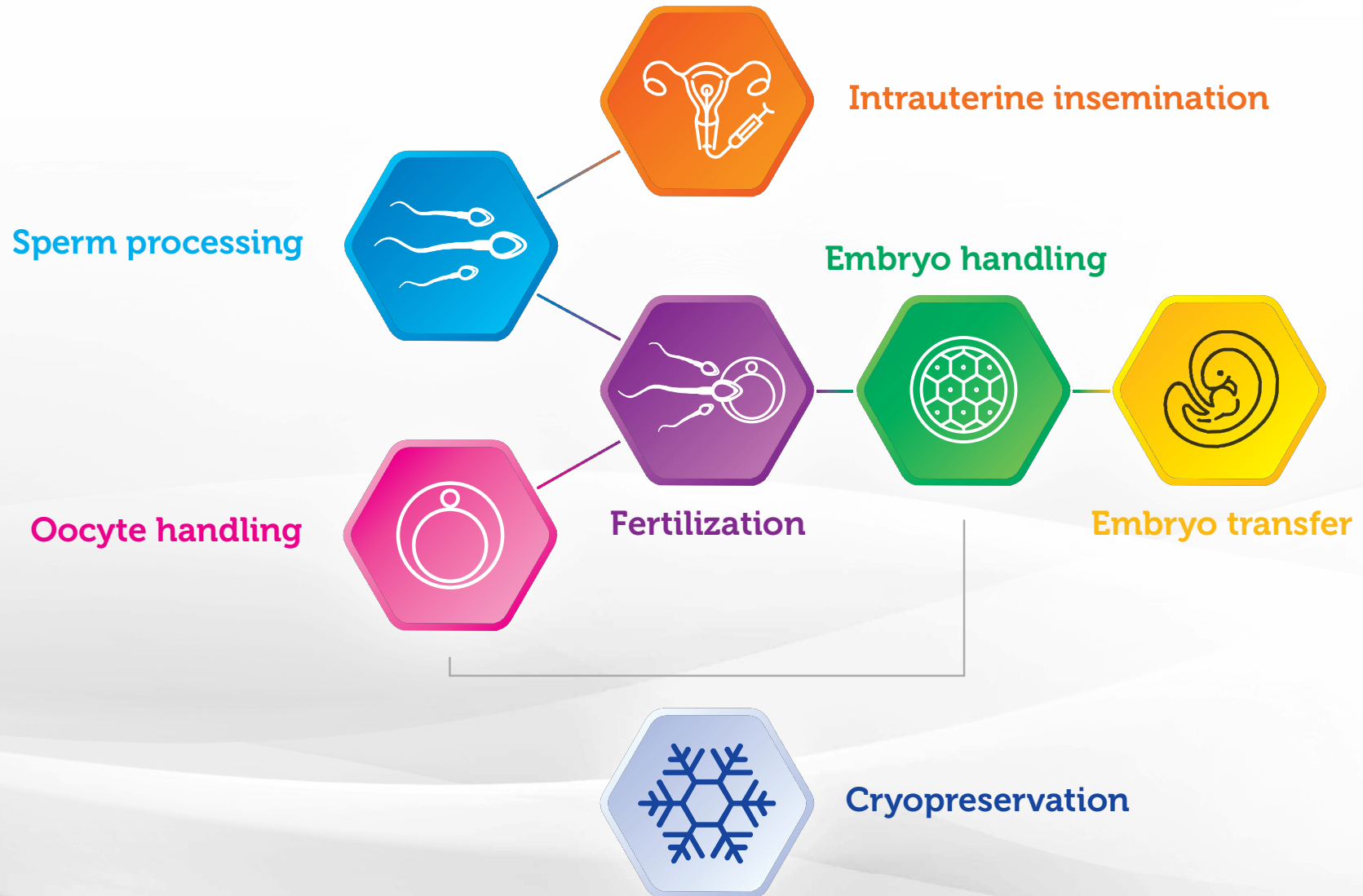


Semen analysis: product range diagnostics



Assisted Reproductive Technologies: ART media





Semen analysis: product range diagnostics

Morphology

p. 8 Spermac Stain

Presence of white blood cells

p. 12 LeucoScreen

Immunology

p. 9 SpermMar Test IgA & IgG

Function of accessory glands

p. 13 EpiScreen Plus
p. 14 Fructose Test
p. 15 Citric Acid Test

Vitality

p. 10 VitalScreen
p. 11 Hypo-osmotic Swelling Test

Assisted Reproductive Technologies: ART media



Sperm processing

Washing/swim-up

- p. 18 FertiCult Flushing medium
- p. 20 Sil-Select Plus Sperm Washing/
Insemination medium

Density gradient separation

- p. 20 Sil-Select Plus
- p. 22 Sil-Select STOCK

Sperm processing for ICSI

- p. 23 10% PVP in FertiCult Flushing medium



Intrauterine insemination

- p. 18 FertiCult Flushing medium
- p. 20 Sil-Select Plus Sperm Washing/
Insemination medium



Oocyte handling

Pick-up

- p. 24 FertiCult Aspiration medium

Washing

- p. 18 FertiCult Flushing medium
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Denudation

- p. 25 Hyaluronidase in FertiCult Flushing medium



Fertilization

- p. 26 FertiCult IVF medium
- p. 28 GAIN medium Early Stage
- p. 30 FertiCult Mineral Oil



Embryo transfer

- p. 18 FertiCult Flushing medium
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Embryo handling

- Embryo culture**
 - p. 28 GAIN medium Early Stage
 - p. 28 GAIN medium Blastocyst
- Culture overlay**
 - p. 30 FertiCult Mineral Oil
- Embryo washing**
 - p. 18 FertiCult Flushing medium



Cryopreservation

- Sperm cryopreservation**
 - p. 31 SpermFreeze
 - p. 32 SpermFreeze SSP
- Oocyte cryopreservation**
 - p. 33 FertiVit Cooling / FertiVit Warming
- Embryo cryopreservation**
 - p. 33 FertiVit Cooling / FertiVit Warming
 - p. 34 VitriFreeze ES / VitriThaw ES
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 - p. 36 EmbryoFreeze / EmbryoThaw



FertiCult Flushing medium

HEPES buffered cell culture medium for use in human A.R.T.

PRODUCT

FertiCult Flushing medium is a chemically balanced salt solution (HEPES buffered) with 4 g/Liter human serum albumin (EMA, Ph Eur, USP, FDA approved), used for oocyte washing, embryo replacement, sperm injection in ICSI, sperm washing, density gradient preparation and swim-up techniques in human IVF.

FertiCult Flushing medium is available with or without phenol red and/or gentamicin.

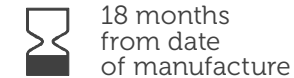


* exposure at zygote stage

PRODUCT SPECIFICATIONS

pH (under air)	7.30 - 7.90 (release criteria: 7.30 - 7.60)
Osmolality	270 - 290 mOsm/kg
Sterility	SAL 10^{-3}
Endotoxin	< 0.25 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



REGULATORY

- CE-marked as Class III medical devices by Notified Body 0344
- Health Canada License

PRODUCT ORDER CODES

FertiCult Flushing medium	FLUSH020 – 5x 20ml FLUSH050 – 5x 50ml FLUSH100 – 3x 100ml	FertiCult Flushing medium with phenol red and gentamicin	FLUSH020PRG – 5x 20ml FLUSH050PRG – 5x 50ml FLUSH100PHR_G – 3x 100ml
FertiCult Flushing medium with phenol red	FLUSH020PHR – 5x 20ml FLUSH050PHR – 5x 50ml FLUSH100PHR – 3x 100ml	Sil-Select Plus Sperm Washing/ Insemination medium Sil-Select Plus Sperm Washing/ Insemination medium with gentamicin	WASH020 – 1x 20 ml WASH100G – 1x 100 ml



Sil-Select Plus

Sperm preparation media



PRODUCT

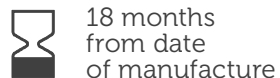
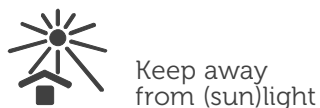
Sil-Select Plus is FertiPro's in-house developed gradient system for semen preparation. Sil-Select Plus is a solution of silane-coated silica particles in Earle's Balanced Salts Solution (EBSS) with HEPES (pH buffer). Extensive tests during the design phase have shown that the product is non-cytotoxic and non-irritant with a non-significant allergenic potential. Sil-Select Plus is manufactured from raw colloidal silica, with full control over each step in the production process. Sil-Select Plus are ready-to-use dilutions of Sil-Select Stock.



PRODUCT SPECIFICATIONS

	SIL-SELECT PLUS UPPER LAYER	SIL-SELECT PLUS LOWER LAYER	SIL-SELECT PLUS 80%
pH (under air)	7.20 - 7.90 (release criteria: 7.20 - 7.60)	7.20 - 7.90 (release criteria: 7.20 - 7.60)	7.20 - 7.90 (release criteria: 7.20 - 7.60)
Osmolality	310 - 340 mOsm/kg	320 - 350 mOsm/kg	310 - 330 mOsm/kg
Sterility	SAL 10 ⁻³	SAL 10 ⁻³	SAL 10 ⁻³
Endotoxin	< 0.5 EU/ml	< 0.5 EU/ml	< 0.5 EU/ml
Density	—	1.105 - 1.115 g/ml	1.097 - 1.107 g/ml
Sperm Survival Test	≥ 80% motility recovery after exposure		
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)		
Ingredients	Where applicable Ph Eur or USP grade raw materials are used		
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C		

STORAGE



REGULATORY

- CE-marked as Class IIb medical devices by Notified Body 0344
- Health Canada License
- Cleared by US FDA

PRODUCT ORDER CODES

SIP008	Sil-Select Plus – 8 preparations*	SIP100	Sil-Select Plus – 2x 100ml
SIP016	Sil-Select Plus – 16 preparations*	SIP80_100	Sil-Select Plus 80% – 100ml
SIP020	Sil-Select Plus – 2x 20ml		
SIP050	Sil-Select Plus – 2x 50ml		

Single bottles can be ordered separately.

* include bottles Sil-Select Plus Sperm Washing/Insemination medium



Sil-Select STOCK

Sperm preparation media

PRODUCT

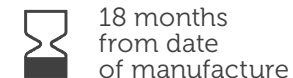
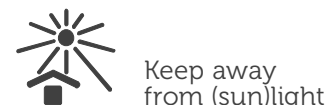
Sil-Select STOCK is an isotonic gradient for semen preparation with a density of approximately 1.12g/ml. It consists of silane-coated colloidal silica particles suspended in HEPES-buffered EBSS (Earle's balanced salt solution). Extensive tests during the design phase have shown that the product is non-cytotoxic and non-irritant with no significant allergenic potential. Sil-Select STOCK medium is an isotonic solution that is used to prepare density gradients of varying densities (e.g. 40-80% or 45-90% dual gradient).



PRODUCT SPECIFICATIONS

pH (under air)	7.20 - 7.90 (release criteria: 7.20 - 7.60)
Osmolality	300 – 330 mOsm/kg
Sterility	SAL 10 ⁻³
Endotoxin	< 0.5EU/ml
Density	1.115 - 1.125 g/ml
Sperm Survival Test	≥ 80% motility recovery after exposure
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



REGULATORY

- CE-marked as Class IIb or Class III (when supplemented with gentamicin) medical devices by Notified Body 0344
- Health Canada License
- Cleared by US FDA

PRODUCT ORDER CODES

SIS100	Sil-Select STOCK – 100ml
SIS500	Sil-Select STOCK – 500ml
SIS100G	Sil-Select STOCK with gentamicin – 100ml



10% PVP in FertiCult Flushing medium

Viscous medium for use in ICSI procedures

PRODUCT

10% PVP in FertiCult Flushing medium is used in human ICSI procedures. The viscosity of the product is such that optimal slowing of the spermatozoa is obtained for easy pick-up of individual cells. The PVP that is used as the source material for the product is of pharmaceutical grade (Ph Eur).




PRODUCT SPECIFICATIONS


* exposure at zygote stage

pH (under air)	7.20 - 7.90 (release criteria: 7.20 - 7.60)
Osmolality	280 - 340 mOsm/kg (release criteria: 280 - 320 mOsm/kg)
Sterility	SAL 10 ⁻³
Viscosity	> 170cP @ 25°C
Endotoxin	< 1.00 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE

 Store between 2-8°C

 Keep away from (sun)light

 9 months from date of manufacture

REGULATORY

- CE-marked as Class III medical devices by Notified Body 0344
- Health Canada License

PRODUCT ORDER CODES

- PVP0.2S 10% PVP in FertiCult Flushing medium (screw cap) – 5x 0.2ml
- PVP1 10% PVP in FertiCult Flushing medium – 1x 1ml



FertiCult Aspiration medium

HEPES buffered cell culture medium for human oocyte pick-up and follicular flushing

PRODUCT

FertiCult Aspiration medium is a ready to use formulation for oocyte pick-up and follicular flushing. FertiCult Aspiration medium contains heparin (pharmaceutical grade) and HEPES to stabilize the pH under air, no CO₂ incubation is required.



PRODUCT SPECIFICATIONS

* exposure at zygote stage

pH (under air)	7.30 - 7.90 (release criteria: 7.30 - 7.60)
Osmolality	270 - 290 mOsm/kg
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



Store between 2-25°C



Keep away from (sun)light



18 months from date of manufacture

REGULATORY

CE-marked as a Class III medical device by Notified Body 0344

PRODUCT ORDER CODES

- ASPI020 FertiCult Aspiration medium – 5x 20ml
- ASPI050 FertiCult Aspiration medium – 5x 50ml
- ASPI100 FertiCult Aspiration medium – 5x 100ml



Hyaluronidase in FertiCult Flushing medium

Hyaluronidase solution

PRODUCT

Hyaluronidase in FertiCult Flushing medium contains 80 IU/ml pharmaceutical grade hyaluronidase in FertiCult Flushing medium. The solution is used in the oocyte denudation process. Hyaluronidase digests the hyaluronic acid between the cumulus cells, which makes it easier to remove the cumulus mechanically.



PRODUCT SPECIFICATIONS

* exposure at zygote stage

pH (under air)	7.30 - 7.90 (release criteria: 7.30 - 7.60)
Osmolality	270 - 290 mOsm/kg
Sterility	SAL 10 ⁻³
Endotoxin	< 1.00 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE

Store between 2-8°C

Keep away from (sun)light

12 months from date of manufacture

REGULATORY

CE-marked as a Class III medical device by Notified Body 0344

PRODUCT ORDER CODES

- HYA001 Hyaluronidase in FertiCult Flushing medium – 5x 1ml
- HYA010 Hyaluronidase in FertiCult Flushing medium – 1x 10ml



FertiCult IVF medium

Fertilization medium



PRODUCT

FertiCult IVF medium is a bicarbonate buffered cell culture medium for fertilization by IVF or ICSI. The composition of this medium fulfills the needs of gametes in preparation of, and during fertilization. FertiCult IVF medium contains 4g/Liter human serum albumin (EMA, Ph Eur, USP, FDA approved) and 50 IU/Liter insulin.

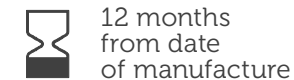
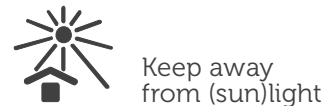


PRODUCT SPECIFICATIONS

* exposure at zygote stage

pH (@ 37°C in 6% CO ₂)	7.20 - 7.50
Osmolality	270 - 290 mOsm/kg
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



PRODUCT ORDER CODES

FertiCult IVF medium FECU020 – 5x 20ml
 FECU050 – 5x 50ml
 FECU100 – 3x 100ml

FertiCult IVF medium FECU020PHR – 5x 20ml
 with phenol red FECU050PHR – 5x 50ml
 FECU100PHR – 3x 100ml

FertiCult IVF medium FECU020PHR_G – 5x 20ml
 with phenol red FECU050PHR_G – 5x 50ml
 and gentamicin FECU100PHR_G – 3x 100ml



GAIN medium Early Stage GAIN medium Blastocyst



Cell culture media
for use in human A.R.T.



PRODUCT

GAIN media are a set of 2 chemically defined, ready to use, sequential cell culture media for use in human in vitro fertilization. The media contain 3.5 g/Liter human serum albumin (EMA, Ph Eur, USP, FDA approved), gentamicin and low concentrations of phenol red.

GAIN medium Early Stage is a suitable environment for gametes and has been developed for use as fertilization medium and embryo culture medium till 4-cell stage.

GAIN medium Blastocyst is optimized for culture from 4-cell stage up till expanded blastocyst stage. Alternatively, the medium can be used immediately after fertilization, up till expanded blastocyst stage. GAIN medium Blastocyst is also suitable for embryo transfer.

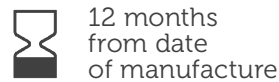
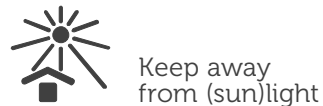


PRODUCT SPECIFICATIONS

* exposure at zygote stage

pH (@37°C – 5% CO ₂)	7.20 - 7.45
Osmolality	270 - 290 mOsm/kg
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



REGULATORY

CE-marked as Class III medical devices by Notified Body 0344

PRODUCT ORDER CODES

GAIN010ES	GAIN medium Early Stage – 1x 10ml
GAIN010BL	GAIN medium Blastocyst – 1x 10ml



FertiCult Mineral Oil

Pre-washed, light mineral oil

PRODUCT

FertiCult Mineral Oil is pre-washed, pharmaceutical grade, light paraffin oil. The oil is washed twice with ultra purified water (Ph Eur) and filtered over a 0.2 µm filter for sterilisation. FertiCult Mineral Oil is used as a culture overlay. The product functions as a temperature/gas exchange buffer, and avoids evaporation culture medium.



PRODUCT SPECIFICATIONS


* exposure at zygote stage

Sterility	SAL 10 ⁻³
Density	0.83 - 0.86 g/ml
Viscosity	< 30cP @ 30°C
Endotoxin	< 0.1 EU/ml
Peroxide value	< 0.1 mEq/kg
Mouse embryo assay*	≥ 80% blastocysts formed after 120h incubation
Water	FertiCult Mineral Oil is washed with ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 28 days after opening, when sterile conditions are maintained and the products are stored at room temperature.

STORAGE

+15°C  +25°C
Store between 15-25°C

 Keep away from (sun)light

 18 months from date of manufacture

REGULATORY

- CE-marked as a Class IIa medical device by Notified Body 0344
- Cleared by US FDA

PRODUCT ORDER CODES

MINOIL050	FertiCult Mineral Oil – 1x 50ml
MINOIL100	FertiCult Mineral Oil – 1x 100ml
MINOIL500	FertiCult Mineral Oil – 1x 500ml



SpermFreeze

Medium for freezing human spermatozoa

PRODUCT

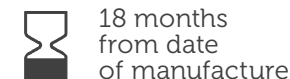
SpermFreeze is a single step freezing medium for use with human sperm cells. The medium is clear (does not contain any milk, egg yolk,...) and ready to use.



PRODUCT SPECIFICATIONS

pH (under air)	7.20 - 7.90 (release criteria: 7.20 - 7.60)
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25 EU/ml
Sperm survival test	≥ 80% motility recovery after exposure
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



REGULATORY

- CE-marked as a Class III medical device by Notified Body 0344
- Cleared by US FDA
- Health Canada License

PRODUCT ORDER CODES

SPF05	SpermFreeze – 25x 5ml
SPF	SpermFreeze – 5x 20ml



SpermFreeze SSP

Medium for freezing human spermatozoa

PRODUCT

SpermFreeze SSP has a higher glycerol concentration which allows the semen to be stored in fewer freezing straws compared to the standard SpermFreeze. Importantly, the end concentration of glycerol in the sperm straws is not higher when the instructions for use are strictly followed.





PRODUCT SPECIFICATIONS

pH (under air)	7.20 - 7.90 (release criteria: 7.20 - 7.60)
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25 EU/ml
Sperm survival test	≥ 80% motility recovery after exposure
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE

 Store between 2-8°C

 Keep away from (sun)light

 18 months from date of manufacture

REGULATORY

CE-marked as a Class III medical device by Notified Body 0344

PRODUCT ORDER CODE

SSP001 SpermFreeze SSP – 5x 1ml



FertiVit Cooling FertiVit Warming

Kits for vitrification and warming of human oocytes and embryos up till blastocyst stage

PRODUCT

FertiVit Cooling and FertiVit Warming kits are sets of cell culture media designed for the vitrification and warming of human oocytes and embryos from 2PN up till blastocyst stage (different protocols are described in the instructions for use). The media are optimized and validated for use with closed vitrification systems (e.g. High Security Vitrification straws from CBS). Both kits consist of 6 media, but not all media are needed for embryo vitrification.



PRODUCT SPECIFICATIONS

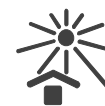
pH (under air)	7.20 - 7.50 (release criteria: 7.20-7.40)
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

* exposure to all the media in sequence at zygote stage

STORAGE



Store between 2-8°C



Keep away from (sun)light



12 months from date of manufacture

REGULATORY

CE-marked as a Class III medical device by Notified Body 0344

PRODUCT ORDER CODES

- FVC_KIT FertiVit Cooling – 4 procedures
- FVW_KIT FertiVit Warming – 4 procedures



VitriFreeze ES VitriThaw ES

Kits for vitrifying and warming
of human embryos

PRODUCT

VitriFreeze ES / VitriThaw ES kits are sets of cell culture media designed for the vitrification and warming of 2PN up till blastocyst stage, human embryos. The media are optimized to work with both aseptic (closed) and non-aseptic (open) vitrification devices (separate protocols). The vitrification kit consists of 4 media and the warming kit contains 5 media.

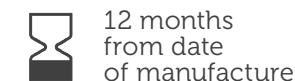


PRODUCT SPECIFICATIONS

* exposure to all the media
in sequence at zygote stage

pH (under air)	7.20 - 7.40
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



REGULATORY

CE-marked as a Class III medical device by Notified Body 0344

PRODUCT ORDER CODES

VF_KIT1_ES VitriFreeze ES – 4 procedures
VT_KIT1_ES VitriThaw ES – 4 procedures



VitriFreeze VitriThaw

Kits for vitrifying and warming of human blastocysts

PRODUCT

VitriFreeze and VitriThaw kits are sets of cell culture media designed for the vitrification and warming of human blastocysts. The media are suitable for use with non-aseptic (open) vitrification devices.

The vitrification kit consists of 3 media and the warming kit contains 4 media.



PRODUCT SPECIFICATIONS

* exposure at zygote stage

pH (under air)	7.20 - 7.40
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



REGULATORY

- CE-marked as a Class III medical device by Notified Body 0344
- US FDA Clearance

PRODUCT ORDER CODES

VF_KIT1	VitriFreeze – 4 procedures
VT_KIT1	VitriThaw – 4 procedures



EmbryoFreeze EmbryoThaw

Medium for freezing and thawing of human embryos

PRODUCT

EmbryoFreeze and EmbryoThaw media are PBS/propanediol based cell culture media for (slow) freezing and thawing of human embryos. These media can be used with 2PN up till 4-cell stage human embryos.

The kit has been designed with a 1-step freezing and 3-step thawing protocol.

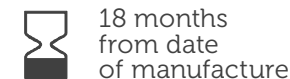


PRODUCT SPECIFICATIONS

* exposure at zygote stage

pH (under air)	7.20 - 7.40
Sterility	SAL 10 ⁻³
Endotoxin	< 0.25 EU/ml
Mouse embryo assay*	≥ 80% blastocysts formed after 96h incubation
Water	All FertiPro media are manufactured using ultra purified water (Ph Eur)
Ingredients	Where applicable Ph Eur or USP grade raw materials are used
In-use stability	Can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C

STORAGE



REGULATORY

CE-marked as a Class III medical device by Notified Body 0344

PRODUCT ORDER CODES

EMF30_P	EmbryoFreeze/Thaw – 30 procedures
EMF40_T_P	EmbryoThaw – 40 procedures
EMF120_F_P	EmbryoFreeze – 12 vials