

SilSelect Plus

Sil-Select Plus™

Gradient system for semen preparation

Sterilized using
aseptic processing techniques.

STERILE A

USED ABBREVIATIONS

ICSI Intracytoplasmic Sperm Injection
IVF In Vitro Fertilization
IUI Intra Uterine Insemination

INTENDED USE AND COMPOSITION

Sil-Select Plus is a gradient system for semen preparation. Sil-Select Plus gradients consist of silane-coated colloidal silica particles suspended in HEPES-buffered EBSS (Earle's balanced salt solution). The Sil-Select Plus system can be used in combination with IUI, IVF and ICSI.

MATERIAL INCLUDED WITH THE KIT

Product code: SIP008 (8 preparation kit)

- » 8 x 2.5ml Sil-Select Plus LOWER LAYER
- » 8 x 2.5ml Sil-Select Plus UPPER LAYER
- » 8 x 5ml Sil-Select Plus WASHING/INSEMINATION medium

Product code: SIP008PRG

- » same as SIP008 but washing medium contains phenol red and gentamicin

Product code: SIP016 (16 preparation kit)

- » 2 x 20ml Sil-Select Plus LOWER LAYER
- » 2 x 20ml Sil-Select Plus UPPER LAYER
- » 5 x 20ml Sil-Select Plus WASHING/INSEMINATION medium

Product code: SIP016PRG

- » same as SIP016 but washing medium contains phenol red and gentamicin

Product code: SIP020 (2x20ml)

- » 1 x 20ml Sil-Select Plus LOWER LAYER
- » 1 x 20ml Sil-Select Plus UPPER LAYER

Product code: SIP050 (2x50ml)

- » 1 x 50ml Sil-Select Plus LOWER LAYER
- » 1 x 50ml Sil-Select Plus UPPER LAYER

Product code: SIP100 (2x100ml)

- » 1 x 100ml Sil-Select Plus LOWER LAYER
- » 1 x 100ml Sil-Select Plus UPPER LAYER

Product code: SIP080_100 Sil-Select Plus 80%

- » 1x 100ml Sil-Select Plus 80% solution

Product code: SIP080_500 Sil-Select Plus 80%

- » 1x 500ml Sil-Select Plus 80% solution

Single bottles are all CE marked (Notified Body number 0344).
Single bottles of Sil-Select Plus can be ordered separately.

MATERIAL NOT INCLUDED WITH THE KIT

- » 3cc syringes with 1 1/2" 21g needle
- » Centrifuge (must be able to operate for up to 30 minutes at 400g)
- » Incubator or water bath at 37°C (optional)
- » SIPO20/SIPO50/SIP100/SIPO80_100/SIPO80_500
- » Washing /Insemination medium
- » LAF bench (ISO Class 5)

PRODUCT SPECIFICATIONS

- » pH: 7.20-7.90 (Release criteria: 7.20-7.60)
- » Osmolality: 310-340mOsm/kg (Upper layer)
320-350mOsm/kg (Lower layer)
- » Density: 1.1050-1.1150 g/ml (Lower layer)
- » Viscosity: < 1.65 cP (Lower layer)
- » Endotoxin: < 0.5EU/ml
- » Sterility: SAL 10⁻³
- » Sperm Survival test: ≥ 80% survival after 45 minutes exposure of spermatozoa to the test medium
- » Not MEA tested
- » A certificate of analysis and MSDS are available upon request.

CALCULATION OF G-FORCES

The g-force of your centrifuge can be calculated using this formula:

$$g = 1.118 \times r \times \text{rpm}^2 \text{ or } \text{rpm} = \text{Square root } (g / (1.118 \times r))$$

r = radius of centrifuge in mm
rpm = rotations per minute / 1000

- » Example 1
r = 100 mm
rpm = 1800 rotations per minute
g = 1.118 x 100 x 3.24 = 362g

- » Example 2
r = 100 mm
g = 350g
rpm = $\text{SQR } (350 / (1.118 \times 100)) = 1.77$
rpm = 1770 rotations per minute

INSTRUCTIONS FOR USE WITH FRESH SEMEN SAMPLES

1. Bring all components of the system and samples to room temperature or to 37°C.
2. Transfer 2.5ml of Sil-Select Plus Upper Layer into a sterile disposable centrifuge tube.
3. Using a 3cc syringe with a 1 1/2" 21g needle, place 2.5ml of Sil-Select Plus Lower Layer under the Upper Layer. Take care that the two layers are distinctly separated. This is done by placing the tip of the needle on the bottom of the test tube and slowly dispensing the Sil-Select Plus Lower Layer. This two layer gradient is stable for up to two hours.
4. Gently place up to 2.5ml of liquefied semen onto the upper layer using a transfer pipette or syringe.
5. Centrifuge for 15 to 18 minutes at 350g to 400g. When this centrifugation is completed you may not be able to visibly see a pellet. If so, it is essential to continue the procedure with a second centrifugation of 3 to 5 minutes.
6. Remove supernatant down to the pellet.
7. Using a syringe, add 2-3ml of sperm washing medium and re-suspend the pellet.
8. Centrifuge for 8 to 10 minutes at 300g. Higher sperm concentration will require the maximum 10 minutes centrifugation to ensure a complete and thorough sperm wash.
9. Remove supernatant down to the pellet and repeat steps 7 and 8.
10. Remove supernatant and replace with a suitable volume of appropriate medium.

INSTRUCTIONS FOR USE WITH FROZEN SEMEN SAMPLES

1. Bring all components of the kit and samples to room temperature or to 37°C.
2. Transfer 1ml of Sil-Select Plus Upper Layer into a sterile disposable centrifuge tube.
3. Using a 3cc syringe with a 1 1/2" 21g needle, place 1ml of Sil-Select Plus Lower Layer under the Upper Layer. Take care that the two layers are distinctly separated. This is done by placing the tip of the needle on the bottom of the test tube and slowly dispensing the Sil-Select Plus Lower Layer. This two-layer gradient is stable for up to two hours.
4. Gently place the thawed semen sample onto the Upper Layer using a transfer pipette or syringe (0.5ml maximum).
5. Centrifuge for 15-20 minutes at 350g.
6. Remove supernatant down to no less than the 0.5ml mark above the pellet.
7. Using a syringe, add 2-3ml of sperm washing medium and resuspend the pellet.
8. Centrifuge for 8 to 10 minutes at 300g.
9. Remove supernatant down to the pellet and repeat steps 7 and 8.
10. Remove supernatant and replace with a suitable volume of appropriate medium.

If samples do not liquefy and therefore do not pass through the layers, increasing the centrifugal force up to, but no more than, 500 g will help to separate the sperm.

PRE-USE CHECKS

- » Do not use the product if seal of the container is opened or defect when the product is delivered.
- » Do not use the product if it has changed colour or shows any evidence of microbial contamination.

STORAGE AND CONSERVATION

Store products without gentamicin between 2-25°C before first use. Store products with gentamicin between 2-8°C. Open and close bottles under aseptic conditions (e.g. LAF bench, ISO Class 5). The products can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C. Do not freeze. Do not use after expiry date. Content cannot be re-sterilized after opening.

WARNINGS AND PRECAUTIONS

All human, organic material should be considered potentially infectious. Handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens. Always work under strict hygienic conditions (e.g. LAF-bench ISO Class 5) to avoid possible contamination, even when the products contain gentamicin. SIPO08PRG and SIPO16PRG contain gentamicin sulphate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

TECHNICAL SUPPORT

 FertiPro N.V.
Industriepark Noord 32, 8730 Beernem, Belgium
Tel +32 (0)50 79 18 05
Fax +32 (0)50 79 17 99
URL: www.fertipro.com
E-mail: info@fertipro.com

Sil Select Stock

Sil-Select Stock™

Stock solution for semen preparation

Sterilized using
aseptic processing techniques.

STERILE A

USED ABBREVIATIONS

ICSI Intracytoplasmic Sperm Injection
IVF In Vitro Fertilization
IUI Intra Uterine Insemination

INTENDED USE AND COMPOSITION

Sil-Select Stock is an isotonic gradient for semen preparation with a density of approximately 1.12g/ml.
Sil-Select Stock consists of silane-coated colloidal silica particles suspended in HEPES-buffered EBSS (Earle's balanced salt solution). Sil-Select Stock can be used in combination with IUI, IVF and ICSI.

MATERIAL INCLUDED WITH THE KIT

Product code: SIS100
» 1 x 100ml Sil-Select Stock

Product code: SIS500
» 1 x 500ml Sil-Select Stock

Product code: SIS5000
» 10 x 500ml Sil-Select Stock

Product code: SIS100G
» 1 x 100ml Sil-Select Stock with gentamicin

Product code: SIS500G
» 1 x 500ml Sil-Select Stock with gentamicin

MATERIAL NOT INCLUDED WITH THE KIT

- » 3cc syringes with 1 1/2" 21g needle
- » Centrifuge (must be able to operate for up to 30 minutes at 400g)
- » Incubator or water bath at 37°C (optional)
- » FertiCult Flushing Medium
- » LAF bench (ISO Class 5)

PRODUCT SPECIFICATIONS

- » pH: 7.20-7.90 (Release criteria: 7.20-7.60)
- » Osmolality: 300-330mOsm/kg
- » Density: 1.1150 – 1.1250 g/ml
- » Viscosity: < 1.75 cP
- » Endotoxin: < 0.5EU/ml
- » Sterility: SAL 10⁻³
- » Sperm Survival test: ≥ 80% survival after 45 minutes exposure of density selected spermatozoa to the test medium
- » Not MEA tested
- » A certificate of analysis and MSDS are available upon request

CALCULATION OF G-FORCES

The g-force of your centrifuge can be calculated using this formula:

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INSTRUCTIONS FOR PREPARATION OF GRADIENTS

We advice to prepare a dual gradient system (45%-90% or 40%-80%) starting from Sil-Select Stock. If preferred a multi-layer can be used as well (e.g. 45%-70%-90%). To prepare a 90% gradient, mix 1 part FertiCult Flushing medium with 9 parts Sil-Select Stock.
A 45% gradient is prepared by mixing 5.5 parts FertiCult Flushing medium with 4.5 parts Sil-Select Stock.
Alternatively any HEPES-buffered EBSS-based medium can be used for the preparation of the gradients.
Note: Gradients should be prepared and repacked under sterile conditions (e.g. LAF bench ISO Class 5). For optimal results, prepare the gradients maximum 24 hours prior to use. Mix well after diluting the Sil-Select Stock solution.

INSTRUCTIONS FOR USE WITH FROZEN SEMEN SAMPLES

1. Bring all components of the kit and samples to room temperature or to 37°C.
2. Transfer 2.5ml of the low density gradient (40%- 45%) into a sterile disposable centrifuge tube.
3. Using a 3cc syringe with a 1 1/2" 21g needle, place 2.5ml of the high density gradient (80%-90%) under the first layer. Take care that the two layers are distinctly separated. This is done by placing the tip of the needle on the bottom of the test tube and slowly dispensing the high density gradient. This two-layer gradient is stable for up to two hours.
4. Gently place up to 2.5ml of liquefied semen onto the upper layer using a transfer pipette or syringe.
5. Centrifuge for 15-18 minutes at 350g to 400g. When this centrifugation is complete you may not be able to visibly see a pellet. If so, it is essential to continue the procedure with a second centrifugation of 3 minutes.
6. Remove supernatant down the pellet.
7. Using a syringe, add 2-3ml of sperm washing medium and re-suspend the pellet.
8. Centrifuge for 8 to 10 minutes at 300g. Higher sperm concentrations will require the maximum 10 minutes centrifugation to ensure a complete and thorough sperm wash.
9. Remove supernatant down to the pellet and repeat steps 7 and 8.
10. Remove supernatant and replace with a suitable volume of appropriate medium.

PRE-USE CHECKS

- » Do not use the product if seal of the container is opened or defect when the product is delivered.
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Store products between 2-25°C before first use. Open and close bottles under aseptic conditions (e.g. LAF-bench, ISO Class 5). The products can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C. Do not freeze. Do not use after expiry date. Content cannot be re-sterilized after opening.

WARNINGS AND PRECAUTIONS

All human, organic material should be considered potentially infectious. Handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens.
Always work under strict hygienic conditions (e.g. LAF bench ISO Class 5) to avoid possible contamination.
In case Sil-Select Stock medium contains gentamicin, appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

TECHNICAL SUPPORT

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