



Sil>Select Plus™

INTENDED USE AND COMPOSITION

Sil>Select Plus is a ready-to-use gradient system for semen preparation.

- The following gradients are available:
- Sil>Select Plus Upper layer (45%)
- Sil>Select Plus 80%
- Sil>Select Plus Lower layer (90%)

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

FROZEN SEMEN SAMPLES

Mix the density gradient bottles by 5 bottle inversions before use.

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The following gradients are available:

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- Sil>Select Plus 80%
- Sil>Select Plus Lower layer (90%)

Sil>Select Plus consists of silane-coated colloidal silica particles suspended in HEPES-buffered EBSS (Earle's balanced salt solution) supplemented with 0.4-2.2g/l human serum albumin (medicinal substance derived from human blood plasma). Some product codes are supplemented with 10mg/l Gentamicin (medicinal substance). The Sil>Select Plus system can be used for semen preparation for Intra Uterine Insemination (IUI), In Vitro Fertilization (IVF) and IntraCytoplasmatic Sperm Injection (ICSI).

Sil>Select Plus Sperm Washing/Insemination medium is intended for use in assisted reproductive technologies, more specifically sperm washing/holding for the production of semen gradients. The medium can be used for IUI. Sil>Select Plus Sperm Washing/Insemination medium is a HEPES-buffered medium which also contains bicarbonate, physiologic salts, glucose, lactate and human serum albumin (4.0g/L medicinal substance derived from human blood plasma). The product is also available with phenol red and gentamicin (10mg/L medicinal substance).

For professional use only.

PRODUCT SPECIFICATIONS

Sil>Select Plus Upper layer/Lower layer/80% media:

- Chemical composition
- pH criteria: 7.20-7.90 (release criteria: 7.20-7.60)
- Osmolality: 280-310 mOsm/kg (Upper layer)
- 290-330 mOsm/kg (Lower layer)
- Density: 1.0500-1.0700 (Upper layer)
- 1.1050-1.1150 g/ml (Lower layer)
- 1.097-1.107 g/ml (80%)

• Endotoxin test by Limulus Ameboocyte Lysate methodology (USP <85%): < 0.2EU/ml

• Sterility test according to the current Ph. Eur. 2.6.1/ USP <71%: No growth

• Centrifuge for 8 to 10 minutes at 300g.

• Remove supernatant down to the pellet and repeat steps 7 and 8.

• Remove supernatant and replace with a suitable volume of appropriate medium.

STORAGE/DISPOSAL INSTRUCTIONS

Sil>Select Plus

• Store products without gentamicin between 2-25 °C. Once opened: store between 2-8 °C.

• Store products with gentamicin between 2-8 °C.

• The products can be used up to 7 days after opening when sterile conditions are maintained and the products are stored at 2-8 °C.

• Keep away from (sun)light.

• The products are stable after transport (max. 5 days) at elevated temperatures (≤ 37 °C).

• Dosage de survie des spermatozoïdes humains (mortalité en % comparée à l'échantillon de contrôle après 4 heures): ≥ 80%

• Dosage de survie des spermatozoïdes humains (mortalité en % comparée à l'échantillon de contrôle après 24 heures): ≥ 75%

• Non testé sur embryons de souris.

• Utilisation de produits de la pharmacopée européenne (Ph Eur) ou américaine (USP) le cas échéant.

• Un certificat d'analyse et une fiche de données de sécurité sont disponibles sur demande ou peuvent être téléchargés sur notre site Internet (www.fertiplus.com).

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PRODUCT SPECIFICATIONS

Sil>Select Plus Upper layer/Lower layer/80% media:

- Chemical composition
- pH criteria: 7.20-7.90 (release criteria: 7.20-7.60)
- Osmolality: 280-310 mOsm/kg (Upper layer)
- 290-330 mOsm/kg (Lower layer)
- Density: 1.0500-1.0700 (Upper layer)
- 1.1050-1.1150 g/ml (Lower layer)
- 1.097-1.107 g/ml (80%)

• Endotoxin test by Limulus Ameboocyte Lysate methodology (USP <85%): < 0.2EU/ml

• Sterility test according to the current Ph. Eur. 2.6.1/ USP <71%: No growth

• Human sperm survival assay (% motility compared with control after 4 hours): ≥ 80%

• Human sperm survival assay (% motility compared with control after 24 hours): ≥ 75%

• Not MEA tested

• Use of Ph Eur or USP grade products if applicable

• A certificate of analysis and MSDS are available upon request or can be downloaded from our website (www.fertiplus.com)

Sil>Select Plus Sperm Washing/Insemination medium:

- Chemical composition
- pH criteria: 7.30-7.90 (release criteria: 7.30-7.60)
- Osmolality: 270-290 mOsm/kg

• Endotoxin test by Limulus Ameboocyte Lysate methodology (USP <85%): < 0.25EU/ml

• Sterility test according to the current Ph. Eur. 2.6.1/ USP <71%: No growth

• Centrifuge for 8 to 10 minutes at 300g.

• Remove supernatant down to the pellet and repeat steps 7 and 8.

• Remove supernatant and replace with a suitable volume of appropriate medium.

STERILE A

Document ID: FP09 I13_Plus R01 E.6

Update: 01/08/2022

MATERIAL INCLUDED/

MATERIAL INCLUS/

MATERIAL INCLUIDO/

MATERIAL INCLUIDO/

ΥΛΙΚΟ ΤΟΥ ΠΕΡΙΑΛΜΑΝΤΑΙ/

MATERIAAL AANWIJZIG



STERILE A

Document ID: FP09 I13_Plus R01 E.6

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MATERIAL INCLUDED/

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ΜΑΤΕΡΙΑΛ ΙΝΚΛΟΥΔΟ/

MATERIAAL INCLUIDO/

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MATERIAAL AANWIJZIG

Catalogue number	Bestellnummer	Número de catálogo	Número di catalogo	Ajelska katalognummer	Catalogusnummer
SIP008	8 x 2.5ml	Sil>Select Plus® Lower layer	Sil>Select Plus® Upper layer	Sil>Select Plus®	Sil>Select Plus®
SIP016	2 x 20ml	Sil>Select Plus® Lower layer	Sil>Select Plus® Upper layer	Sil>Select Plus®	Sil>Select Plus®
SIP008PRG	8 x 2.5ml	Sil>Select Plus® Lower layer	Sil>Select Plus® Upper layer	Sil>Select Plus®	Sil>Select Plus®
SIP016PRG	2 x 20ml	Sil>Select Plus® Lower layer	Sil>Select Plus® Upper layer	Sil>Select Plus®	Sil>Select Plus®

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