SpermFilter®

PRODUCT INFORMATION

Stock solution 100%

Catalogue no. *Without Phenol red and Gentamicin*	
SPF100-0010	10 ml
SPF100-0050	50 ml
SPF100-0100	100 ml
SPF100-0250	250 ml
SPF100-0500	500 ml

Catalogue no. *With Phenol red and Gentamicin*	
SPF100-0010RG	10 ml
SPF100-0050RG	50 ml
SPF100-0100RG	100 ml
SPF100-0250RG	250 ml
SPF100-0500RG	500 ml

Ready-to-use Gradient 80%

Catalogue no. *With Phenol red and Gentamicin*	
SPF80-0010	10 ml
SPF80-0050	50 ml
SPF80-0100	100 ml
SPF80-0250	250 ml
SPF80-0500	500 ml

Ready-to-use Gradient 45%

Catalogue no. *With Phenol red and Gentamicin*	
SPF45-0010	10 ml
SPF45-0050	50 ml
SPF45-0100	100 ml
SPF45-0250	250 ml
SPF45-0500	500 ml

Application
SpermFilter® is a silane coated silica particles colloidal suspension medium for semen preparation in IUI, IVF, ICSI.

Composition
SpermFilter® is composed of silica particles covalently coated with silane suspended in HEPES buffered EBSS (Earle's balanced salt solution).
SpermFilter® is an isotonic gradient with a density of +/- 1.12g/ml.

Material not included
- 3cc syringes with 1½″ 21g needle
- SpermWash medium
- Centrifuge (must be able to operate for up to 30 minutes at 100g)
- Optional: incubator or water bath at 37°C
- LAF Bench (ISO Class 5)

Quality Control
- pH: 7,20 – 7,90
- (Release criteria: 7,20 – 7,60)
- Osmolality: 300 - 330 mOsm/kg (100% stock solution)
  310 - 340 mOsm/kg (45% gradient)
  310 - 330 mOsm/kg (80% gradient)
- Endotoxin: < 0,5 EU/ml
- Sterility: SAL 10-3
- Density: 1,1150 – 1,1250 g/ml (100% stock solution)
  1,0970 – 1,1070 g/ml (80% gradient)
- Viscosity: < 1.75 cP (100% stock solution)
  < 1.65 cP (80% gradient)
- Sperm Survival Test ≥ 80% (after 45 minutes exposure of density selected spermatozoa to the test medium)
- Not MEA tested
- Certificate of Analysis and MSDS are available upon request.

Sterility
SpermFilter® is sterilized by using aseptic processing techniques. STERILE A

Calculation of G-Forces
Use the following formula in order to calculate the g-force for your centrifuge:

$$g = 1.118 \times r \times rpm^2$$

OR

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

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 = SQR {350 / (1.118 x 100)} = 1.77
rpm = **1770 rotations per minute**

Precautions and Warnings
Always work under hygienic conditions (LAF-bench ISO Class 5) to avoid possible contamination.
Always wear protective clothing when working with specimens.
Handle specimens as if capable of transmitting HIV or hepatitis.
All human organic material should be considered potentially infectious.
In case the product contains gentamicin, appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

SpermFilter®

Pre-use checks
Do not use if the seal on the bottle is broken or open when the product is delivered.
Do not use if the product shows any signs of microbial contamination or has changed colour.
Mix the density gradient bottle by 5 bottle inversions before use.

Storage & Conservation
Store products without gentamicin: between 2º-25ºC before first use. After opening store between 2°-8ºC.
Store products with gentamicin: between 2°-8ºC.
Use aseptic working procedures during opening and closing of the bottles ((LAF-bench, ISO Class 5). Avoid freezing.
Do not use after expiry date.
Do not freeze.
After opening the container, do not use the product longer than 7 days. Sterile conditions must be maintained and product must be stored at 2º - 8º C.
Cannot be re-sterilized after opening.
Stable after transport (up to 5 days) at elevated temperatures (≤ 37°C).

Technical Support

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Distributor:

SpermFilter®

Instructions for use

Instructions preparation of gradients
Dilution of SpermFilter® Stock Solution 100%

We recommend to prepare a two-layer gradient system (e.g. 45%-90% or 40%-80%) starting from SpermFilter® Stock Solution 100%. If preferred a multi-layer gradient system can also be used (e.g. 45%-70%-90%).

Preparing a 90% gradient:
Mix 1 part SpermWash® with 9 parts SpermFilter® Stock Solution 100%.
Preparing a 45% gradient:
Mix 5.5 parts SpermWash® with 4.5 parts SpermFilter® Stock Solution 100%.

Alternatively, any HEPES-buffered EBSS-based medium can be used for the preparation of the gradients.

Note: Prepare and repack the gradients under sterile conditions (e.g. LAF bench, ISO Class 5). Prepare the gradients max 24 hours prior to use. Mix well after diluting the SpermFilter® Stock Solution 100%.

Instructions fresh semen samples

1. Bring all components of the system and samples to room temperature or 37°C.
2. Place 2.5ml SpermFilter® upper layer (40% - 45%) into a sterile disposable centrifuge tube.
3. Place 2.5ml SpermFilter® lower layer (80% - 90%) beneath the upper layer by using a 3cc syringe with a 1½″ 21g needle. The two layers must be distinctly separated. Do this by placing the tip of the needle on the bottom of the test tube and slowly dispense the SpermFilter® lower layer. The two layer gradient remains stable for up to two hours.
4. Carefully place up to 2.5ml of liquefied semen onto the upper layer by using a transfer pipette or syringe.
5. Centrifuge at 350g to 400g for 15 to 18 minutes. In case you do not see a visible pellet afterwards continue the procedure with a second centrifugation for 3 to 5 minutes.
6. Aspirate the supernatant down to the pellet.
7. Add with a syringe 2-3ml SpermWash® medium and re-suspend the pellet.
8. Centrifuge at 300g for 8 to 10 minutes. A higher sperm concentration will require the maximum 10 minutes centrifugation to ensure a complete and thorough sperm wash.
9. Aspirate the supernatant down to the pellet and repeat steps 7 and 8.
10. Aspirate the supernatant and resuspend with a suitable volume of appropriate medium.

Instructions frozen semen samples

1. Bring all components of the system and samples to room temperature or 37°C.
2. Place 1.0ml SpermFilter® upper layer (e.g. 45%) into a sterile disposable centrifuge tube.
3. Place 1.0ml SpermFilter® lower layer (e.g. 80%) beneath the upper layer by using a 3cc syringe with a 1½″ 21g needle. The two layers must be distinctly separated. Do this by placing the tip of the needle on the bottom of the test tube and slowly dispense the SpermFilter® lower layer. The two layer gradient remains stable for up to two hours.
4. Carefully place up thawed semen sample onto the upper layer by using a transfer pipette or syringe (max. 0.5ml)
5. Centrifuge at 350g for 15 to 20 minutes.
6. Aspirate the supernatant down to no less than the 0.5ml mark above the pellet.
7. Add with a syringe 2-3ml SpermWash® medium and re-suspend the pellet.
8. Centrifuge at 300g for 8 to 10 minutes.
9. Aspirate the supernatant down to the pellet and repeat steps 7 and 8.
10. Aspirate the supernatant and resuspend with a suitable volume of appropriate medium.

In case samples do not liquefy, causing no passage through the layers, increase the centrifugal force up to, but no more than, 500g in order to separate the sperm.

SYMBOL	MEANING
REF	Catalogue number
LOT	Batch code
	Use by (expiry date)
	Temperature limitations
STERILE A	Sterile medical device processed using aseptic technique (filtration)
	Consult instructions for use
CE	CE mark

Used Abbreviations

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