

SpermWash®

PRODUCT INFORMATION

SpermWash® medium

Catalogue no.

SW-0002	2 ml
SW-0010	10 ml
SW-0050	50 ml
SW-0100	100 ml
SW-0250	250 ml
SW-0500	500 ml

Application

SpermWash® is used for swim up techniques of human spermatozoa, introduction of washed spermatozoa into the uterus during IUI, for sperm injection into oocytes during ICSI, to wash the spermatozoa and/or for diluting stock solution of silica-based density-gradients. SpermWash® can also be used for washing of human oocytes, embryos and embryo transfer.

The medium contains HEPES so there is no need for CO₂ incubation. The medium is complete and does not need further additives. The medium does not contain heparin.

The medium must be pre-incubated in the incubator for 12 hours before use with closed lid.

Composition

SpermWash® is a HEPES buffered medium which contains bicarbonate, physiologic salts, glucose, lactate, HSA (Human Serum Albumin, 4.00g/L), phenol red and gentamicin.

SpermWash® is ready-to-use.

Material not included

- Syringe (e.g. 1ml Plastipack)
- Catheter
- Petri dishes
- Test tubes
- Incubator at 37°C (No CO₂)
- Microscope
- LAF Bench (ISO Class 5)

Quality Control

- pH: 7,30 – 7,60 (Release criteria)
- Osmolality: 270 – 290 mOsm/kg
- Endotoxin: < 0.25 EU/ml
- Sterility: sterile, SAL 10⁻³
- MouseEmbryo Assay: ≥ 80% after 30 min exposure (blastocysts after 96h, zygote stage)
- Chemical composition
- Use of Ph Eur or USP grade products if applicable
- Certificate of Analysis and MSDS are available upon request.

Sterility

SpermWash® is sterilized by using aseptic processing techniques. **STERILE | A**

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.

Ensure that the patient is not sensitized to the antibiotic gentamicin.

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.

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, has changed colour or cloudy.

Storage Conditions

Store refrigerated (2° - 8°C).

Do not use after expiry date.

Do no freeze before use.

Keep away from (sun)light.

After opening the container, do not use the product longer than 7 days. Sterile conditions must be maintained and product must be stored at 2° - 8° C.

Stable after transport (up to 5 days) at elevated temperatures (≤ 37°C).

Technical Support



Gynotec B.V.

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Distributor:

SpermWash®

Instructions for use

Washing spermatozoa (Suggested procedure)

Before use, SpermWash® can be preheated to room temperature or 37°C.

- Add 5ml SpermWash® to the native semen sample and mix. Centrifuge the preparation at approximately 300g for 15 minutes.
- Aspirate the supernatant and leave about 0.5ml sperm pellet in the bottom of the centrifuge tube.
- Add 5ml SpermWash® to the sperm pellet. Mix carefully until the pellet is completely dissolved.
- Centrifuge the preparation at 300g for 10 minutes.
- Perform a swim-up.

Swim-up








(According to WHO, 2010)

- Carefully layer 1,5ml SpermWash® on top of 1ml washed semen in a conical based centrifuge tube.
- Place the tube in the incubator at a 45° angle for 1 hour at 37°C.
- Place the tube carefully in an upright position and remove 1,0ml of the top layer.
- Dilute the aliquot of motile cells with 8 volumes of SpermWash®. Centrifuge for 15 minutes at 300g.
- Carefully aspirate the supernatant and resuspend the sperm pellet in 0,5ml SpermWash® medium.

Embryo transfer

(According to Brinsden, 2005)

- Take a sterile syringe, fill it with SpermWash® and eject air bubbles. Place the syringe onto a catheter and eject the medium.
- Suck up the SpermWash® into the syringe and push down the piston to the 10µl calibration mark.
- Suck up the embryo(s) into the catheter in such a way that the volume is approximately 20-30µl.
- Hand over catheter and syringe to the clinician for insertion and transfer into the uterus.

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

Used Abbreviations

ICSI	Intracytoplasmatic Sperm Injection
IUI	Intra Uterine Insemination