

PureSperm® 100

Intended Use: Summary and Explanation

PureSperm®100 is a sterile (autoclaved SAL-10⁻³) colloidal silica suspension in an isotonic salt solution. It is optimised for the preparation of density gradients for the separation and purification of human sperm for use in Assisted Reproduction Technologies (ART). This system effectively separates normal sperm from lymphocytes, epithelial cells, abnormal or immature sperm, cell debris, bacteria and seminal fluid.

Components

Silane-coated silica	Purified water
Potassium chloride	HEPES
Calcium chloride	EDTA
Sodium chloride	Glucose

Performance Characteristics

pH	7.4-7.8
Osmolality (mOsm/kg H ₂ O)	300-310
Endotoxin transfer during treatment	<1.0 EU/mL
Human sperm survival 18 hours after density gradient separation	>70%

Bottles and stoppers are M.E.A. tested

Storage and Stability

Store unopened bottles at 2 to 40°C and avoid temperatures above or below these values. Under these conditions PureSperm®100 has a shelf-life of 24 months. The expiry date is shown on both bottles and cartons.

Open and close bottles under aseptic conditions. After opening store at 2 to 8°C when not in use. Shelf-life on the product label applies when the product is stored according to manufacturer's recommendations.

No antibiotics, unstable additives or preservatives have been added by the manufacturer to PureSperm®100.

Precautions and Warnings

- When retrieving the sperm pellet, follow the instructions given in the pack insert to avoid inadvertent contamination
- Use aseptic procedures at all times
- If available, use sealed buckets during centrifugation to avoid creation of aerosols
- Clean accidental spills using a dampened cloth or paper. PureSperm®100 causes floors and benches to be extremely slippery
- PureSperm®100 does not represent any kind of fire or combustion hazard. A material safety data sheet is available from the distributor or manufacturer (see nidacon.com)
- Do not use any solution which shows evidence of bacterial contamination or if stopper accidentally comes in contact with unsterile surfaces
- Do not use contents if tamper-evident seal is broken
- Not for drug, household or other uses. Avoid ingestion and contact with eyes.
- Federal Law (USA) restricts this device to sale by or on the order of a physician
- Please check for regulatory compliance governing the use of ART products in your country

Ordering Information

Volume	Article No.
100mL	PS100-100
250mL	PS100-250
1000mL	PS100-1000



www.nidacon.com

For further technical information or assistance, please contact your distributor or the manufacturer.


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Recommendations

Prepare two PureSperm® gradients for each semen sample. This reduces the risk of overloading a single gradient, provides security when handling tubes or recovering sperm pellets and provides two tubes to balance the centrifuge rotor.

Reagents and Equipment

- PureSperm®100 , PureSperm® Buffer and PureSperm®Wash
- Bench top centrifuge with swing out rotor
- Disposable sterile conical centrifuge tubes
- Sterile pipettes

Procedure for preparation of PureSperm® gradients and sperm separation

Bring all solutions to room temperature.

1. Add 2mL PureSperm® Buffer to 8mL PureSperm®100 to form 10mL 80% PureSperm®
2. Add 6mL PureSperm® Buffer to 4mL PureSperm®100 to form 10mL 40% PureSperm®
3. Use a pipette with a sterile tip to add 2 mL of 80% PureSperm® to a conical centrifuge tube
4. Use a new sterile pipette tip to carefully layer 2mL 40% PureSperm® on top of the 80% PureSperm®
5. Use a sterile pipette to carefully layer liquefied semen (up to 1.5mL) onto the PureSperm®
6. Centrifuge at 300 x g for 20 minutes. Do not use the brake. Calculate the correct RPM for your centrifuge
7. Use a new sterile Pasteur pipette and aspirate, in a circular movement from the surface, everything except the pellet and 4-6mm of 80% PureSperm®. If no pellet is seen after centrifugation, remove all fluid except the lowest 0.5mL
8. Use a new sterile Pasteur pipette to aspirate the pellet (or the lowest 0.5mL liquid). Transfer sperm pellet to new tube and resuspend pellet in 5mL PureSperm®Wash.
9. Centrifuge at 500 x g for 10 minutes. Do not use the brake
10. Aspirate PureSperm®Wash supernatant leaving as little liquid as possible above pellet. If no pellet is seen, leave the bottom 0.25mL fluid
11. Resuspend the sperm pellet in a suitable volume of culture medium to obtain the required sperm concentration. The sperm sample is now ready for analysis or use

