

# PureSperm® 40/80

## Intended Use: summary and explanation

PureSperm®40 and PureSperm®80 are sterile (autoclaved SAL-10<sup>-3</sup>) colloidal silica suspensions in isotonic salt solutions. They are optimised for the preparation of density gradients for the separation and purification of human sperm for use in Assisted Reproduction Technologies (ART). PureSperm®40 should be used with PureSperm®80 to form a two-layer density discontinuous gradient system which effectively separates normal sperm from lymphocytes, epithelial cells, abnormal or immature sperm, cell debris, bacteria and seminal fluid.

## Components

|                      |                 |
|----------------------|-----------------|
| Silane-coated silica | EDTA            |
| Potassium chloride   | Glucose         |
| Sodium chloride      | Sodium Citrate  |
| Purified water       | Calcium lactate |
| HEPES                | Sodium pyruvate |

## Performance Characteristics

|   |            |
|---|------------|
| pH  | 7.4-7.8    |
| Osmolality (mOsm/kg H <sub>2</sub> O)                     | 300-310    |
| Endotoxin transfer during treatment                       | <1.0 EU/mL |
| 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 Pure Sperm® 40 and PureSperm® 80 have 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® 40 and PureSperm® 80.

## 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®40/80 causes floors and benches to be extremely slippery
- PureSperm®40/80 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. |
|----------------------|-------------|
| 20mL PS40, 20mL PS80 | PSK-020     |
| 100mL PS40           | PS40-100    |
| 100mL PS80           | PS80-100    |



[www.nidacon.com](http://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®40, PureSperm®80 and PureSperm®Wash
- Bench top centrifuge with swing out rotor
- Disposable sterile conical centrifuge tubes
- Sterile pipettes

### Procedure for washing sperm with density gradient

Bring all solutions to room temperature.

1. Use a pipette with a sterile tip to add 2mL of PureSperm®80 to a conical centrifuge tube
2. Use a new sterile pipette tip to carefully layer 2mL PureSperm®40 on top of the PureSperm®80
3. Use a sterile pipette to carefully layer liquefied semen (up to 1.5mL) onto the PureSperm®
4. Centrifuge at 300 x g for 20 minutes. Calculate the the correct rpm for your centrifuge. Do not use the brake
5. Use a new sterile Pasteur pipette to aspirate, in a circular movement from the surface, everything except the pellet and 4-6 mm of PureSperm®80. If no pellet is seen after centrifugation, remove all fluid except the lowest 0.5mL.
6. 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
7. Centrifuge at 500 x g for 10 minutes. Do not use the brake
8. Aspirate PureSperm®Wash supernatant leaving as little liquid as possible above pellet. If no pellet is seen, leave the bottom 0.25mL fluid
9. 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

