

Reagents and Equipment

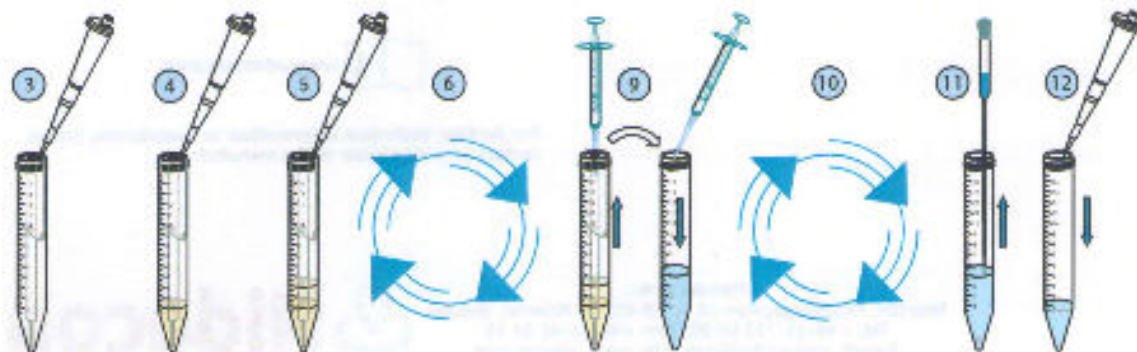
- ProInsert™ Kit
- PureSperm[®] 40
- PureSperm[®] 80
- PureSperm[®] Wash
- Bench top centrifuge with swing out rotor
- Sterile pipette tips (see illustration)
- 1-2 mL sterile syringe

Procedure for using ProInsert™

1. Bring all solutions to room temperature and open all products under aseptic conditions
2. Open a ProInsert™ Kit and remove the centrifuge tube containing the ProInsert™
3. Using a pipette with sterile tip, add 2 mL of PureSperm[®] 80 to the outer channel at the top of the ProInsert™. The gradient material will run down into the ProInsert™ chamber, out through a hole at the bottom of the chamber, and down the wall of the centrifuge tube to form a layer at the bottom of the centrifuge tube
4. Repeat number 3 above, using a new sterile pipette tip and PureSperm[®] 40, again via the outer channel, thereby creating a 2-layer density gradient
5. Once again, use another sterile pipette tip to carefully layer liquefied semen (up to 1.5mL) again via the outer channel and onto the density gradient.
Take care not to touch the edges of the central channel with the semen.

6. Cap the tube and centrifuge at 300 x g for 20 minutes. Do not use the centrifuge brake. Calculate the correct RPM for your centrifuge
7. Add 5mL PureSperm[®] Wash to the second centrifuge tube (not illustrated)
8. Attach the sperm-retrieval pipette from the ProInsert™ Kit to a 1-2 mL syringe, prepare to aspirate the sperm pellet (not illustrated)
9. Pass the pipette **slowly** into the ProInsert™ via the central channel, down to the sperm pellet (see graphic). Be careful not to disrupt the pellet. Using the syringe, aspirate only the sperm pellet. Retract the pipette until the tip of the pipette is safely above the liquid surface, aspirate a little air and then retract the pipette completely from the central channel. (This procedure is to ensure that no contents in the pipette will be lost during transfer to the PureSperm[®] Wash)
10. Centrifuge the PureSperm[®] Wash and the pellet at 500 x g for 10 minutes. Do not use the centrifuge brake
11. Aspirate the PureSperm[®] Wash supernatant, leaving as little liquid as possible above the pellet. If no pellet is seen, leave the bottom 0.25mL fluid
12. Re-suspend the sperm pellet in a suitable volume of culture/transfer medium (e.g. PureSperm[®] Wash) to obtain the required sperm concentration for IVF, ICSI or IUI

The sperm sample is now ready for analysis or use.



ProInsert™

Intended Use: Summary and Explanation

During preparation of sperm from a semen sample using a density gradient separation, the ProInsert™ reduces the risk of recontamination of the sperm pellet during pellet retrieval. The ProInsert™ is a safe and easy-to-use device, designed for use with Nidacon products.

Components

- Centrifuge tube containing the ProInsert™
- Centrifuge tube for washing media (PureSperm Wash™)
- PRP (Pellet Retrieval Pipette)

All components are efficacy and M.E.A. tested, and are packaged in sterilized pouches.

Performance Characteristics

The upper and outer chamber of the ProInsert™ is used for preparing the density gradient, firstly by pipetting in the Bottom-Layer of the gradient, secondly by pipetting in the Top-Layer of the gradient, and thirdly by pipetting in the semen sample.

The central channel is only used for retrieving the sperm pellet using the pipette supplied, and should never be contaminated by the semen sample.

The sperm pellet is transferred to PureSperm Wash™ in the second centrifuge tube, in order to rinse away remains of the gradient material transferred in the pellet, followed by centrifugation (see instructions for use).

Storage and Stability

The unopened ProInsert™ Kit can be stored at room temperature until use.

The manufacturer's batch number, production date and recommended expiry date can be found at the top of the pouch.

Precautions and Warnings

- When retrieving the sperm pellet via the central channel of the ProInsert™, diligently follow the instructions given in the package insert to avoid inadvertent contamination.
- Use aseptic procedures at all times
- All ejaculates should be considered infected and should be handled accordingly.
- If available, use sealed buckets during centrifugation to avoid creation of aerosols
- ProInsert™ Kit 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 if any part of the kit accidentally comes in contact with unsterile surfaces
- Do not use if tamper-evident seal is broken
- Do not re-use
- All components must be discarded with "biological material" after usage.
- Federal Law (USA) restricts this device to sale by or on the order of a medical professional
- Please check for regulatory compliance governing the use of ART products in your country

Ordering Information

One pouch containing 5 individually packaged ProInsert™ kits

Article No.

P115-5



www.nidacon.com

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

Manufacturer:

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