

Indication for Use

ProInsert™ is used during preparation of human sperm from a semen sample using density gradient separation during assisted reproductive procedures. ProInsert™ facilitates density gradient preparation and pellet retrieval following density gradient separation.

Components

- Centrifuge tube containing the ProInsert™
- PRP (Pellet Retrieval Pipette)

Performance Characteristics

Endotoxin level	<1.0 EU/device
Human sperm survival (HSSA) 24 hours after density gradient separation	>80% motility

The outer chamber of the ProInsert™ is used for the preparation of the density gradient.

The central channel is only used for retrieving the sperm pellet using the pipette supplied, and should never come in contact with the semen sample.

The ProInsert™ has been sterilized by radiation.



Temperature limit



Do not reuse



Use by - see label



sterilization by irradiation



Batch code



Consult instructions for use



CE Mark (Conformité Européen)



Date of Manufacture



Manufacturer

Storage and Stability

The unopened ProInsert™ Kit can be stored at 2-27° C temperature until use. Under these conditions ProInsert™ Kit has a shelf-life of 24 months.

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

Precautions and Warnings

- Caution: Federal Law (USA) restricts this device to sale by or on the order of a medical professional
- Single use only (risk for cross contamination)
- Use aseptic procedures at all times
- 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
- All components must be discarded with "biological material" after usage
- Please check for regulatory compliance governing the use of ART products in your country

Contraindication

ProInsert™ Kit is not to be used for sperm gradient preparation for male patients who have sexually transmitted infections.

Ordering Information

One pouch containing 5 individually packaged ProInsert™ kits

Article No.

PI15-5



www.nidacon.com

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



Manufacturer:
Nidacon, Flöjelbergsgatan 16 B, SE-431 37 Mölndal, Sweden
Tel: +46-31-703 06 30, Fax: +46-31-40 54 15
E-mail: contact@nidacon.com, www.nidacon.com



Reagents and Equipment

- ProInsert™ Kit
- PureSperm® 40
- PureSperm® 80
- PureSperm® Wash
- Bench top centrifuge with swing out rotor
- Sterile pipette tips
- 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 chamber 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 chamber, thereby creating a 2-layer density gradient
5. Once again, use another sterile pipette tip to layer liquefied semen (up to 1.5mL) again via the outer chamber and onto the density gradient

Take care not to touch the opening of the central channel with the pipette tip.

If the sample is too viscous, some of the sample may remain in the outer chamber until centrifugation. This does not effect the result

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 pellet retrieval pipette from the ProInsert™ Kit to a 1-2 mL syringe (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). Transfer the pellet to the second tube containing PureSperm® Wash
10. Centrifuge at 500 x g for 10 minutes. Do not use the brake
11. Aspirate the PureSperm® Wash supernatant using a sterile pipette, 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

To achieve the correct g force:

$$Rpm = \sqrt{[(g / (1.118 \times r)) \times 10^3}$$

r = rotational radius, the distance (mm) from the centre of the rotor to the bottom of a centrifuge tube in the bucket when raised to horizontal position

For example; to achieve 300 x g when radius = 165 mm the centrifuge speed must be:

$$Rpm = \sqrt{[(300 / (1.118 \times 165)) \times 10^3} = 1275$$

