SM600
Sperm Select® System
For semen preparation prior to intrauterine insemination

For in-vitro use only

Directions for Use
SM600 Sperm Select® System

For semen preparation prior to intrauterine insemination

DEVICE DESCRIPTION

The Sperm Select System® is a self-contained kit that includes everything needed to prepare a semen sample for intrauterine insemination (IUI). Before IUI, the semen must be prepared to remove white blood cells, bacteria and other undesirable components of the seminal fluid.

WARNINGS

• Store at 2-8° C / 36-47° F
• Protect from freezing
• Remove the Sperm Select System kit from the refrigerator 30 minutes before use.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

US patent no. 4,804,537
INDICATIONS FOR USE
The Sperm Select System is to be used for the separation and recovery of progressively motile spermatozoa from seminal fluid.

KIT CONTENTS
The Sperm Select System includes:

- One Luer-lock glass syringe of Sperm Select. Sperm Select is a sterile, membrane-filtered, non-pyrogenic, mouse embryo assay survival > 80% solution containing highly purified sodium hyaluronate. The sodium hyaluronate is dissolved in a sterile phosphate buffer.
- One vial of Medium, 0.5 ml, sterile, membrane-filtered, non-pyrogenic and mouse embryo assay survival > 80% solution. The phosphate buffered solution contains sodium chloride, magnesium sulphate, and glucose.
- One syringe carrier
- One vial holder
- One name tag
- One “Directions for Use” booklet
- Peel Pack 1:
  - One plastic Luer-lock 3 ml syringe
  - One 20-G needle
  - One 21-G needle with affixed air vent
- Peel Pack 2:
  - One plastic Luer-lock 3 ml syringe
  - One 20-G needle
  - One syringe plug
PRINCIPLE OF PROCEDURE

Sperm from fresh liquefied ejaculate or thawed semen are allowed to swim up and migrate through a mixture of Sperm Select and culture medium.

Due to the viscosity of the mixture of Sperm Select and Medium, the highly progressive motile spermatozoa will reach the upper portion of the solution contained in the preparation vial.

MATERIALS REQUIRED

The materials required for each semen procedure:

• One Sperm Select System Kit
• Sterile container for sperm collection (not provided)
• SM700 Blockheater™ Incubator (not provided)
• Intrauterine insemination catheter (not provided)
• Disposable powder-free surgical-type gloves (not provided)

Materials recommended:

• Sperm counting device

SPECIMEN COLLECTION AND HANDLING

Collect ejaculate using a clean sample container. The ejaculate should be fresh, not more than 1 hour old. The semen should be allowed to liquefy at room temperature.
PREPARATION OF SPECIMEN FOR MIGRATION

1. Open the Sperm Select System kit, take out the contents, and identify each component.

2. Swab the Medium vial septum with a solution of 96% Ethanol. NOTE: DO NOT USE IODINE.

3. Allow to dry.

4. Open Peel Pack 1. Take the Sperm Select glass syringe from the tray and hold it vertically (distal tip upward).

5. Remove the tip cap from the glass syringe and discard.

6. Attach the 20-G needle to the glass syringe. If there is an air bubble in the syringe, DO NOT expel that air bubble.

7. Inject Sperm Select contained in the glass syringe into the Medium vial (Figure 1).

8. Discard the glass syringe in accordance with Federal, State and local Medical/Hazardous waste practices.
9. Gently invert the vial 10 times (Figure 2).

10. Place the vial in the vial-holder.

11. Attach the 21-G needle (the long needle with an air vent affixed to it) to the plastic syringe.

12. To facilitate fine control of the plastic syringe, pull and push the syringe plunger at least once or twice prior to using. This will ensure smooth movement of the plunger inside the syringe barrel.

13. Expel any air present in the syringe.

14. Aspirate 1 ml of liquefied ejaculate (Figure 3).
15. Insert the needle completely into the Medium vial. (This is ensured by pressing the syringe downward until the needle sheath, near the air vent, is FULLY inserted into the vial. When properly inserted, the needle will reach within 4 mm of the bottom of the vial.)

16. SLOWLY inject the ejaculate into the Medium vial, MAKING SURE THAT THE TWO SEPARATE LAYERS ARE MAINTAINED (Figure 4). The ejaculate must fill the vial from the bottom without mixing with the upper layer.

17. Carefully withdraw the needle from the vial by firmly holding the vial and withdrawing the needle with a straight upward movement. DO NOT SHAKE the solution while withdrawing the needle from the vial.

18. Discard the syringe and needle in accordance with Federal, State and local Medical/Hazardous waste practices.

19. Write the patient's name on the enclosed name tag and attach it to the vial prior to incubation.
SPERM MIGRATION DURING INCUBATION

1. Follow the Blockheater™ (incubator) operating instructions.

2. Gently place the vial into one of the cells (Figure 5).

3. Activate the incubation timer. Sperm effectively separate themselves from the rest of the seminal fluid, which normally contains dead sperm, bacteria, and debris.

4. After 45 minutes, the incubator alarm sounds and the cell indicator light flashes. Turn OFF the alarm and blinking light by gently pressing the vial against the bottom of the cell until a soft click is felt.

5. MAKING SURE THAT THE TWO SEPARATE LAYERS ARE MAINTAINED, transfer the vial back to the vial holder.

6. Remove the name tag and save it for further use.
RECOVERY OF PROGRESSIVE MOTILE SPERMATOZOA


2. To facilitate fine control of the plastic syringe, pull and push the syringe plunger at least once or twice prior to using. This will ensure smooth movement of the plunger inside the syringe barrel.

3. Attach the 20-G needle to the syringe, making sure the plunger is fully depressed.

4. Place the syringe into the syringe carrier and ensure that the entire syringe snaps correctly into place.

5. Remove the needle cap.

6. Place the syringe carrier in position over the vial.

7. Insert the needle through the vial septum until the syringe carrier rests on the vial shoulder (Figure 6).

8. While firmly holding the top of the syringe in place (in the carrier) with one hand, SLOWLY push the wings of the syringe down with the other hand until the syringe locks into place.
9. After the syringe is locked into place, ensure that the top of the syringe plunger and the upper portion of the carrier are in an upright position. The syringe should now contain 0.5 ml of processed sperm.

10. Withdraw the syringe and needle with the carrier from the vial by holding the vial and withdrawing the carrier with a straight upward movement.

11. Carefully maintain the syringe plunger in the same position, remove the syringe from the carrier, then detach the needle. Discard the needle in accordance with Federal, State and local Medical/Hazardous waste practices.

12. Put on syringe plug contained in Peel Pack 2 (Figure 7) OR attach the intrauterine insemination catheter to the syringe (Figure 8).

13. Correctly identify the syringe containing the prepared sperm with the patient's name tag.
THE NEXT STEP

The prepared sperm are now ready to be inseminated. Prior to performing the intrauterine insemination, ensure that there is no air left in the syringe or in the catheter. To calculate the concentration of the prepared sperm, take a droplet of prepared sperm from the syringe and examine it in a sperm counting device.
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EXPLANATION OF SYMBOLS

REF  Catalog / Reorder Number

LOT  Batch Code

EXP  Use By (Year-Month)

STERILE EO  Ethylene Oxide Sterilized. Contents sterile (SAL $10^{-6}$) unless package has been opened or damaged.

STERILE A  Membrane Filtered (SAL $10^{-3}$).

Do Not Reuse

See instructions for use.