0609-05

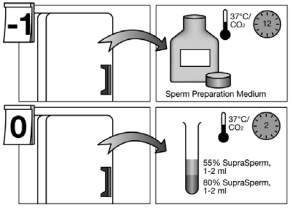
SupraSperm® System

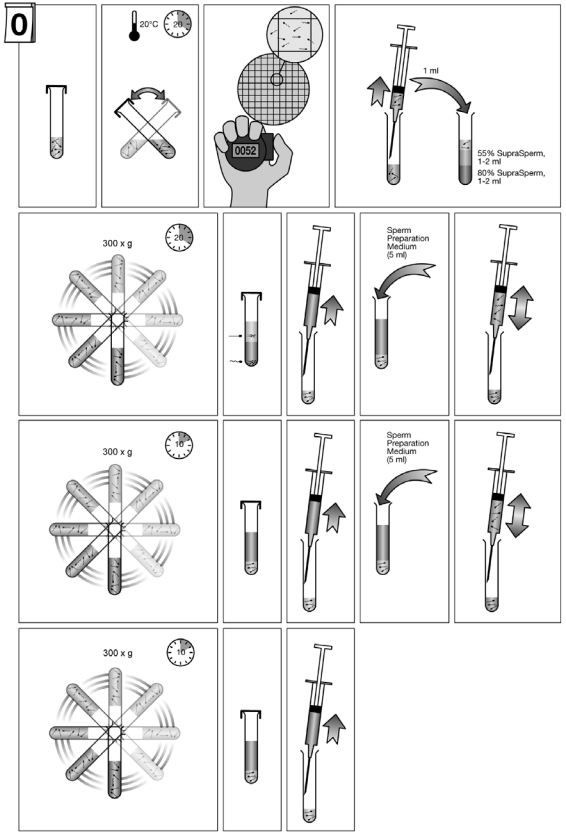
Product No.:
1092

Symbol:

Do not use if package is damaged

Discard excess (unused) media following warming.





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origio

a CooperSurgical Company

SupraSperm® System

Intended use
SupraSperm® is for isolation of viable spermatozoa by the density gradient method.

This product is for ART treatment, whether the cause of infertility is male or female. The product should only be used by professionals trained in ART treatment.

Composition
Supra Sperm® System – 55%:
55% salt solution of colloidal silica particles coated with silane
45% Sperm Preparation Medium with Phenol red

Supra Sperm® System – 80%:
80% salt solution of colloidal silica particles coated with silane
20% Sperm Preparation Medium with Phenol red

Quality control testing
Sterility tested (Ph.Eur., USP)
Osmolality tested (Ph.Eur., USP)
pH tested (Ph.Eur., USP)
Endotoxin tested ≤ 1.0 EU/ml (Ph.Eur., USP)
Sperm Survival Test ≥ 80%
Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability
The products are aseptically processed and supplied sterile.
Store in original container at 2-8°C, protected from light.
When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.
Do not freeze.
The product is provided in vials intended for single use.
Excess (unused) media should be discarded.

Precautions and warnings
Do not use the product if:
1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of ART media has not been determined and is still unknown.

Note: Dispose of the device in accordance with local regulations for disposal of medical devices.

Instructions for use
1. For each semen sample prepare a separate gradient for each 1 ml volume. Each gradient is prepared using 1-2 ml of 55% SupraSperm® underlaid with 1-2 ml of 80% SupraSperm®, and pre-equilibrated in a 5-6% CO_2 environment at 37°C.
   Gradients should be prepared immediately before use for optimal results.
2. The semen sample is thoroughly mixed (i.e. repeated tilting for 20 minutes at room temperature).
3. After the mixing process is completed, sperm concentration and motility should be assessed.
4. Carefully dispense 1 ml of liquefied semen sample on top of the prepared gradient.
   Adding too much sperm will result in overloading and poor separation.
5. The gradient is centrifuged at 300 g for 20 minutes.
6. Remove the supernatant from the pellet and place the pellet in a clean centrifuge tube.
7. Re-suspend the pellet in 5 ml of pre-equilibrated Sperm Preparation Medium and centrifuge again at 300 g for 10 minutes. Aspirate the supernatant.
   Repeat the washing procedure (steps 6 and 7 above)
8. Add a small amount of pre-equilibrated Sperm Preparation Medium and determine motility and concentration of spermatozoa in the washed sample.
9. Finally, re-suspend the washed sperm in a suitable volume of Sperm Preparation Medium.
   When the caps of the tubs are tightened the prepared semen can be kept at room temperature (20-25°) for up to one hour prior to insemination. It is recommended that the sperm sample be wrapped in aluminium foil. Alternatively the unwrapped sperm sample can be stored in a 5-6% CO_2 environment at 37°C.