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SupraSperm® 100

Product No.:
1097

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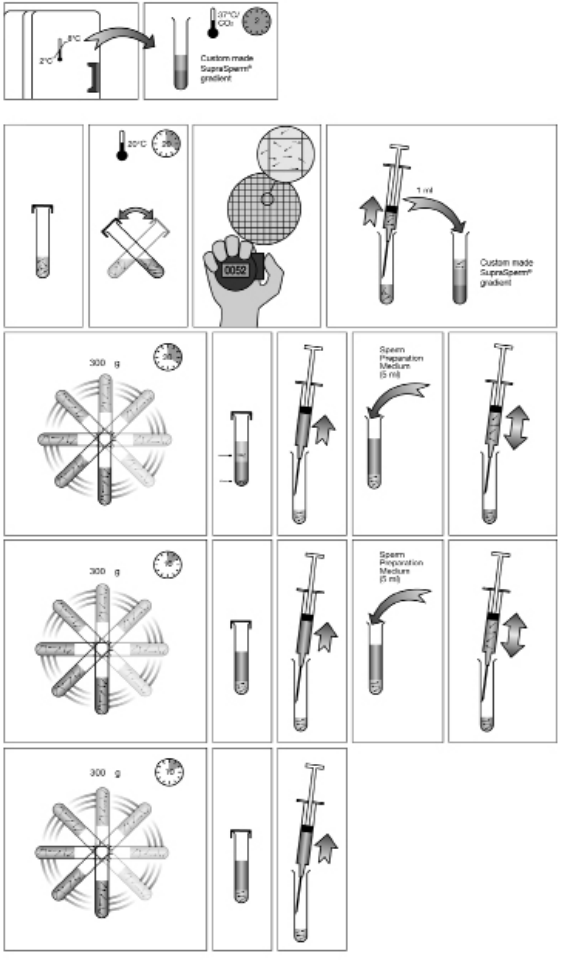
a CooperSurgical Company

Explanation of Symbols (in random order)

	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Do not use if package is damaged
37°C	Discard excess (unused) media following warming
	Indicates the medical device manufacturer
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Indicates the date after which the medical device is not to be used
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified
STERILE A	Indicates a medical device that has been manufactured using accepted aseptic techniques
	Indicates a medical device that needs protection from light sources
	Indicates the need for the user to consult the instructions for use
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions
8 °C 2 °C	Indicates the temperature limits to which the medical device can be safely exposed



SupraSperm® 100

Intended use
SupraSperm® 100 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
Salt solution of colloidal silica particles coated with silane

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.fertility.coopersurgical.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 does not contain any microbial agents and 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.

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 custom gradient preparation use the formula below to prepare a chosen gradient, using SupraSperm® 100 and pre-equilibrated Sperm Preparation Medium.

   X ml SupraSperm® 100
   Y ml Sperm Preparation Medium

   $$\text{Gradient \%} = \frac{X}{X + Y} \times 1.0 \times 100\%$$

2. For each semen sample prepare a separate gradient for each 1 ml volume. Prepare gradients by using 1-2 ml of each custom made SupraSperm® solution and pre-equilibrate in a CO_2 environment at 37°C.
   Gradients should be prepared immediately before use for optimal results.
3. The semen sample is thoroughly mixed (i.e. repeated tilting for 20 minutes at room temperature).
4. After the mixing process is completed, sperm concentration and motility should be assessed.
5. 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.
6. The gradient is centrifuged at 300 g for 20 minutes.
7. Remove the supernatant from the pellet and place the pellet in a clean centrifuge tube.
8. 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 this washing procedure.
9. Add a small amount of pre-equilibrated Sperm Preparation Medium and determine motility and concentration of spermatozoa in the washed sample.
10. Finally, re-suspend the washed sperm in a suitable volume of Sperm Preparation Medium.
11. *When the caps of the tubes 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 CO_2 environment at 37°C.*