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PVP Clinical Grade

Product No.:
1090

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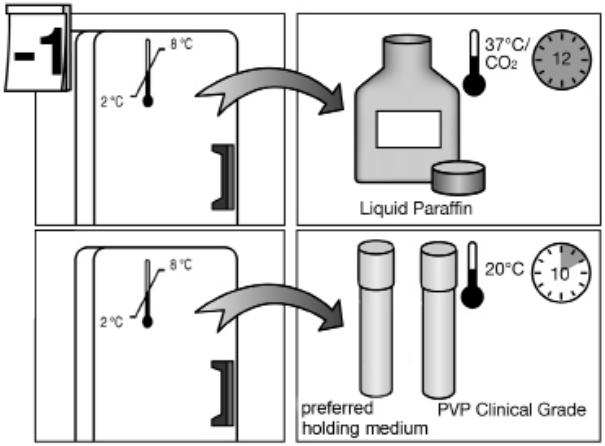
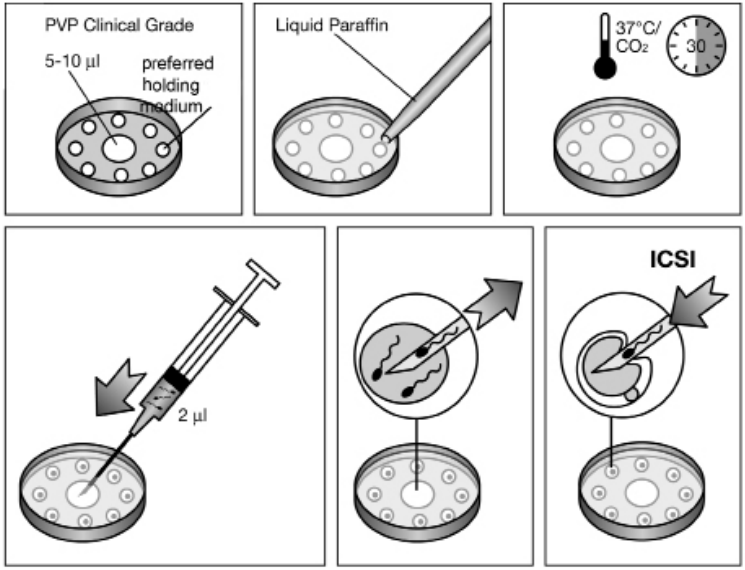
a CooperSurgical Company

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





PVP Clinical Grade

Intended use
PVP Clinical Grade is used for slowing down the movement of the spermatozoa for ICSI.

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
Synthetic Serum Replacement (SSR®)*
(USA: ART Supplement)
* Contains Recombinant Human Insulin
Human serum albumin (HSA)
Polyvinylpyrrolidone
Glucose
Sodium pyruvate
Physiological salts
Sodium bicarbonate
HEPES
Gentamicin sulphate 10µg/ml

Quality control testing
Sterility tested (Ph.Eur., USP)
Osmolality tested (Ph.Eur., USP)
pH tested (Ph.Eur., USP)
Endotoxin tested ≤ 0.2 EU/ml (Ph.Eur., USP)
Sperm Survival Test ≥ 80%
Sperm Immoblisation tested
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 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.

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

Due to native physical characteristics of PVP, small variations in viscosity may occur between batches.
The presence of human serum albumin (HSA) may occasionally cause a small amount of precipitation in the medium.

Instructions for use
1. Remove PVP Clinical Grade and preferred holding medium from storage at 2-8 °C and leave at room temperature for 10 minutes.
2. Depending on the number of oocytes for injection, pipette a corresponding number of 10 µl droplets of preferred holding medium onto the bottom of the ICSI dish.
3. In the middle of the same dish place a 5-10 µl droplet of PVP Clinical Grade.
4. Cover with pre-equilibrated Liquid Paraffin and place the dish in a 5-6% CO_2 environment at 37°C for 30 minutes prior to use.
5. Introduce 2 µl of prepared and washed sperm to the droplet of PVP Clinical Grade. The PVP will reduce the motility of the sperm and facilitate the capture and loading of a single spermatozoon in the injection pipette.