FUJIFILM IrvineScientific

Polyvinylpyrrolidone (PVP)

Lyophilized

Catalog No. 99219 **10 x 1 mL Kits**

For assisted reproductive procedures.

REFERENCES

Atiee S, Pool T, Martin J: A Simple Approach to Intracytoplasmic Sperm Injection. Fertil Steril 63.3, 652-665, 1995.

Van Steirteghen A C, et. al.: High Fertilization and Implantation Rates After Intracytoplasmic Sperm Injection. Human Reproduction 8:7, 1061-1066, 1993.

Glossary of Symbols*:

REF	Catalog Number
LOT	Lot Number
STERILE A	Sterilized using aseptic processing techniques (filtration)
	Expiration: Year - Month - Day
	Caution, consult accompanying documents
	Consult instructions for use
8°C 2°C	Storage Temperature 2-8°C
	Do not re-use
2 STERILIZE	Do not resterilize
	Do not use if package is damaged
	Manufacturer
Rx Only	U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

*Symbol Reference - **EN ISO 15223-1,** Medical devices – Symbols to be used with medical device labels, labeling.

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PN 40495 Rev.11

INDICATION FOR USE

PVP Lyophilized is intended for use in assisted reproductive procedures which include gamete and embryo manipulation. These procedures include the use of PVP medium for immobilizing sperm for ICSI procedures.

DEVICE DESCRIPTION

Polyvinylpyrrolidone has been dissolved in Ultrapure Water and then lyophilized. Each vial contains 100mg of lyophilized PVP. Once reconstituted as directed, it will result in a 10% solution

COMPOSITION

Polymer	Water
Povidone	WFI Quality

QUALITY ASSURANCE

PVP Lyophilized is aseptically processed according to manufacturing procedures which have been validated to meet a sterility assurance level (SAL) of 10^{-3}.

Each lot of PVP is tested for:
- Endotoxin by LAL methodology
- Sperm Motility Recovery Assay
- Sterility by the current USP Sterility Test <71>

All results are reported on a lot-specific Certificate of Analysis which is available upon request.

DIRECTIONS FOR USE

RECONSTITUTION:

1. Using standard aseptic techniques, reconstitute PVP reagent by initially adding 1.0 mL of an appropriate media which is HEPES buffered (such as Sperm Washing Medium already containing 5 mg/mL HSA, Catalog #9983, or Modified Human Tubal Fluid, Catalog #90126, if HSA is not desired in PVP Solution). Small amounts of additional media may be added to obtain desired viscosity.
2. Mix gently to insure complete dissolution of PVP.
   - Prepare product 1 - 2 days prior to intended use to ensure complete dissolution.
   - After aseptic reconstitution, no further filtration is required.
3. Place aliquot of sperm into liquid PVP solution. Fill ICSI pipette with PVP solution and then capture single, immobilized sperm. Sperm is now ready for ICSI procedure.

For additional details on the use of these products, each laboratory should consult its own laboratory procedures and protocols which have been specifically developed and optimized for your individual medical program.

STORAGE INSTRUCTIONS AND STABILITY

Store the unopened vials refrigerated at 2ºC to 8ºC. After reconstitution store PVP media solution at 2°C to 8°C. Discard 21 days after reconstitution.

Do not freeze or expose to temperatures greater than 39°C.

PVP Lyophilized is stable until the expiration date shown on the bottle label when stored as directed.

PRECAUTIONS AND WARNINGS

This device is intended to be used by staff trained in assisted reproductive procedures that include the indicated application for which the device is intended.

Do not use any bottle of medium which shows evidence of particulate matter, cloudiness or is not colorless.

To avoid problems with contamination, handle using aseptic techniques, and discard any excess medium that remains in the bottle after the procedure is completed.

Do not use any bottle in which the sterile packaging has been compromised.