



VitaVitro

VitaVitro® Flushing Buffer Medium

INDICATION FOR USE

VitaVitro® Flushing Buffer Medium is intended for use during ovarian follicle flushing and oocyte collection procedures for use in in vitro fertilization procedures.

COMPOSITION

Physiological salts, Energy (glucose, lactate, pyruvate), Buffer system, Taurine, Sodium citrate, Amino acids, Glutamine dipeptide, EDTA, Phenol red, Gentamicin*.

*from therapeutic-grade source material.

STORAGE CONDITIONS

Store in original container at 2-8°C. Do not freeze.

The shelf life is 12 months from time of manufacture.

Keep away from (sun) light.

Do not use after the expiry date shown on the label.

PERFORMANCE

- Sterility: Sterile(USP<71>)
- Osmolality : 260-290 mOsm/kg (USP <785>)
- pH: 7.2-7.6(USP <791>)
- Endotoxin : <0.25EU/mL (USP <85>)
- 1-cell Mouse Embryo Assay (MEA) : ≥ 80% expanded blastocyst at 96 hours after a 2-hour exposure to media.

DESCRIPTION OF ISO SYMBOLS

The symbol glossary is in line with the SDO-developed standard ANSI/AAMI/ISO 15223-1: Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.

Reference number of symbol	Symbols	Title of symbol	Description of symbol
5.3.2		Keep away from sunlight	Indicates a medical device that needs protection from light sources.
5.1.1		Manufacturer	Indicates the medical device manufacturer.
5.1.3		Date of manufacture	Indicates the date when the medical was manufactured.
5.3.7		Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
5.1.4		Use-by date	Indicates the date after which the medical device is not to be used.
5.1.5		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.2.2		Sterilized using aseptic processing technique	Indicates a medical device that has been manufactured using accepted aseptic techniques.
5.4.2		Do not re-use	Indicates a medical device that is intended for one single use only.

WARNING

- 1) VitaVitro® Flushing Buffer Medium contains the antibiotic Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
- 2) Always work under strict sterile operation to avoid possible contamination, even when VitaVitro® Flushing Buffer Medium contains Gentamicin.
- 3) Only for the intended use.
- 4) Not for use in injections.
- 5) Do not use the product if it becomes discolored, cloudy or shows any evidence of microbial contamination.
- 6) For prescription use only.
- 7) Single Use only – discard media after opening.

INSTRUCTIONS

- 1) Pre-warm VitaVitro® Flushing Buffer Medium to 37°C prior to use.
- 2) Rinse the aspiration needle lumen and tubing using VitaVitro® Flushing Buffer Medium and discard the rinsed fluid.
- 3) The aspirated follicles must be collected in a sterile, non-toxic tube. Keep the tube at 37°C heating block throughout the entire process of oocyte recovery and transport to the embryology laboratory.
- 4) Syringes used for flushing the follicle are filled with VitaVitro® Flushing Buffer Medium. Aspirate the follicular fluid and flush the follicle with a volume of medium equivalent to the amount of follicular fluid collected.

- 5) Wash oocytes with VitaVitro® Flushing Buffer Medium or pre-equilibrated culture medium, taking care to remove any blood clots, debris and granulosa cells.
- 6) After oocyte collection, transfer oocytes to an appropriate culture medium the lab used.

Each laboratory should define and optimize its own procedures.

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