VitaVitro® Warming Kit User Manual

Specification: See the labels

CAUTION

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

INDICATION FOR USE

VitaVitro® Warming Kit is intended for the warming of human blastocysts that have undergone vitrification using VitaVitro® Vitrification Kit for assisted reproductive technology (ART) procedures.

PRODUCT DESCRIPTION

This product is used for warming vitrified human blastocysts for assisted reproductive technology (ART). It contains three media: Human Holding Medium, Human Warming Solution 1, and Human Warming Solution 2.

COMPONENTS

1) Human Holding Medium (HHM): M199 HEPES Buffered Medium supplemented with 12mg/ml Human Serum Albumin (HSA).
2) Human Warming Solution 1 (HW1): same as HHM solution, plus 1.0M sucrose.
3) Human Warming Solution 2 (HW2): same as HHM solution, plus 0.5M sucrose.
4) The reagent vials are The reagent vials are made of two materials: Polypropylene (PP) for the tube body, and silica gel for the seal ring.

STORAGE CONDITIONS

Store at 2˚C to 8˚C

PRECAUTIONS

1) The user should be a trained professional (e.g. a doctor or embryologist).
2) The user should read and understand the user manual and be trained in the correct procedures before using VitaVitro® Warming Kit.
3) The amount of medium included in this kit is sufficient to process three blastocysts. A new kit will need to be used if more that this number of blastocysts is to be processed.

OTHER MATERIALS THAT ARE REQUIRED BUT NOT INCLUDED

- Stereomicroscope
- Heated stage on microscope
- Heated pad close to the microscope
- 1 x four-well dish (4WD)
- 1 x 35 mm Petri Dish
- Stopwatch or timer
- Liquid nitrogen (LN_2) and liquid nitrogen reservoir
- Pipette

SHELF LIFE

12 months

STERILIZATION METHOD

Aseptic processing (including sterilizing filtration and aseptic filling).

PERFORMANCE

Mouse Embryo Assay(1-cell)	≥ 80% development to blastocyst at 96h
Endotoxin	< 0.25 EU/mL
pH	7.2-7.6
Sterility	Sterile
Osmolality	HHM: 295-315 mOsm/kg HW1: 600-850 mOsm/kg (after dilution with ultrapure water 1:1) HW2: 850-1000 mOsm/kg

EXPLANATION OF 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	Symbol	Title of symbol	Description of symbol
5.3.2		Keep away from sunlight	Indicates a medical device that needs protection from light sources.
5.4.2		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
5.1.1		Manufacturer	Indicates the medical device manufacturer.
5.1.3		Date of manufacture	Indicates the date when the medical device 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	LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.2.2	STERILE A	Sterilized using aseptic processing technique	Indicates a medical device that has been manufactured using accepted aseptic techniques.

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PREPARATION

1) All procedures should be performed at room temperature (25-27˚C).
2) All dishes should be warmed to 25-27˚C.
3) HHM and HW2 should be warmed to 25-27˚C; HW1 should be warmed to 37˚C.

WARNING

1) The long-term safety of embryo cryopreservation is unknown.
2) All blood products should be treated as potentially infectious. This product contains Human Serum Albumin (HSA). It was found negative when testing for antibodies to HIV-1/HIV-2, HCV and HTLV-1/HTLV-2 and non-reactive for HBsAg (HBV) and syphilis. However, no known test can guarantee that products derived from humans will not be infectious.
3) Not for use in injections.
4) Do not use any vials which show evidence of damage, tampering or leaking, or particulate matter and cloudiness.
5) To avoid contamination, only use aseptic technique.
6) Do not reuse. After vial opening any remaining medium should be discarded.

DILUTION AFTER WARMING

1) Pipette 20 μL of the HW1 medium containing the thawed blastocysts. The blastocysts shall be in the middle of the HW1 (see Figure1). Expel the blastocysts to Well 2 containing HW2. The blastocysts and HW1 should be formed into a sandwich pattern (see Figure 2).
2) After 3 minutes, pipette 20 μL of the Well 2 solution with the blastocysts to Well 3. Use the sandwich pattern like step 1. Wait 5 minutes. 5 min
3) Transfer the blastocysts to Well 4 with minimum amount of solution. There is no need to use the sandwich pattern. Wait 5 minutes. 5 min
4) Before performing blastocyst transfer, transfer blastocysts to culture medium for 2-4 hours.

WARMING AND EXPELLING OF BLASTOCYSTS

1) Prepare the warming dish (35 mm Petri Dish) 1 hour in advance. Pipette 3,000 μL of 25-27˚C HW1 and warm it to 37˚C. The amount of medium included in this kit is sufficient to process three blastocysts. A new kit will need to be used if more that this number of blastocysts is to be processed.
2) Transfer the liquid nitrogen reservoir containing the storage devices to be warmed to where the warming procedure will be conducted.
3) Just before warming, pipette 900 μL of 25-27˚C HW2 solution in well 2 of a Nunc four-well dish. Put 900 μL HHM each into wells 3 and 4.
4) Warming of the storage device should be conducted as described in the Instructions for Use for the storage device used.
5) The tip of the storage device containing the vitrified blastocysts is immersed in HW1. Ensure that the blastocysts have been recovered from the storage device.

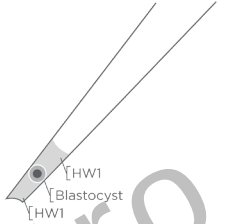

Figure 1. Blastocysts in the middle of HW1

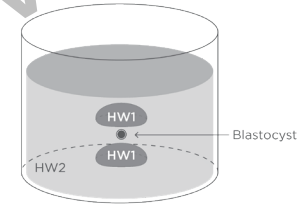

Figure 2. Arrangement of HW1 and HW2 in well 2

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