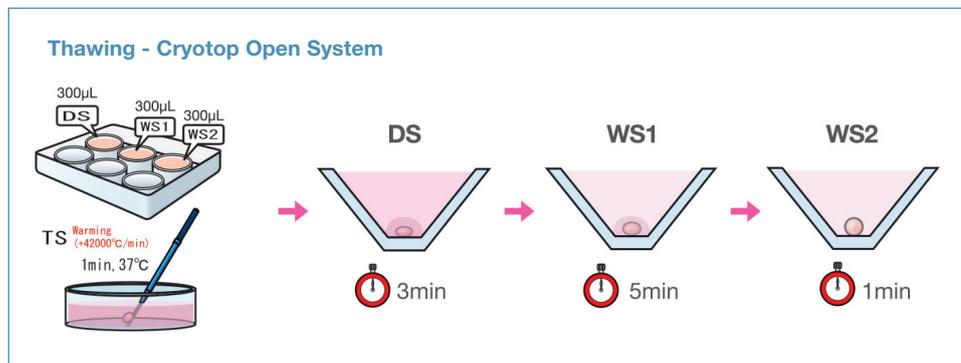




# Thawing Media



## Intended use

This product is to be used for thawing of Oocytes (MII) and embryos.

## Thawing media

- No. 1 (Colour Code: Red) Thawing Solution (TS): 2×4.0 ml vials
- No. 2 (Colour Code: Yellow) Diluent Solution (DS): 1×4.0 ml vial
- No. 3 (Colour Code: White) Washing Solution (WS): 1×4.0 ml vial

**! Caution:** Before use, check the specifications of the container and labeling (number marked on top of the cap, cap colour, vial labeling colour, solution name, and volume). If you notice anything unusual regarding the items mentioned above, do not use the product and please contact the distributor.

## Recommended equipment

- Petri Dish: 35 mm for TS
- ReproPlate: with 6 wells

**! Caution:** This product is sterilised. Please handle the product under sterilisation on a clean bench.

## Instructions for use (IFU)

### Preparation

- Warm TS vial (sealed) with a Petri Dish in an incubator to 37 °C (1.5 hours). Pour the full contents of TS into the Petri Dish.
- Bring DS and WS to room temperature (23-27 °C as recommendation)
- Using a pipette place 300 µl of DS into the first well and 300 µl of WS in both the second and third wells of the Replate.

**! Caution:** Use a sterilised pipette as a handling tool, with a suitable internal diameter for oocytes or embryos. The recommended internal diameters are as follows: 180 µm for oocytes (MII), 180 µm for pronuclear stage embryos, and 250 µm for cleavage or blastocyst stage embryos.

Ki171/V2

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### Thawing

Step 1: Quickly immerse the Cryotop strip completely into the TS. Leave it for 1 minute.

Step 2: Aspirate the oocyte (MII)/embryo with the pipette and gently place it on the BOTTOM of the DS. Leave it for 3 minutes.

Step 3:

1. Aspirate the oocyte (MII)/embryo with the pipette and gently place it on the BOTTOM of the WS of second well. Leave it for 5 minutes.
2. Aspirate the oocyte (MII)/embryo with the pipette, gently place it on the TOP of the WS of third well. After the oocyte (MII)/embryo drops to the bottom of the WS of third well, repeat this process one more time.
3. Transfer the oocyte (MII)/embryo to a culture dish containing the appropriate culture medium. Incubate the oocyte (MII)/embryo in a 37 °C incubator to complete recovery.

**Caution 1:** It is recommended to incubate oocytes (MII) and embryos for 2 hours.

**Caution 2:** Wash the embryo and incubate embryo for recovery in appropriate media to avoid the WS of the third well to be transferred into the patient's body.

### Quality control specification

The following tests were performed for each lot of this product:

- Sterility by the Sterility Test (EP)
- Endotoxin by LAL methodology
- Mouse Embryo Assay (One Cell)
- pH (EP)
- Osmolality (EP)

### Storage instructions and stability

Store the vials at 2 to 8 °C.

This product is stable until the expiry date shown in the labeling on the vial.

### Composition

- HEPES within Basic Culture Medium
- Trehalose
- Hydroxypropyl Cellulose
- Gentamicin

### Contraindication

- Do not re-sterilise
- Do not re-use. Reuse may cause in contamination.
- Do not use solution that shows cloudiness or becomes discoloured.
- Do not use the product if you notice anything unusual regarding the specifications on the label (number, colour, name, volume).
- Device is sterile if the package or container is unopened or undamaged. Do not use if the package or container are opened or damaged.
- Upon delivery media must be stored in original unopened container and refrigerated at 2-8 °C.
- Do not use and please discard if the media were not stored under refrigeration (2 to 8 °C).
- Do not use the product if past the expiration date.

### Warning

- Read the instructions for use prior to use.
- This product is intended to be used by medical specialists trained in fertility treatment.
- Aseptic technique should be used.
- Use sterilised equipment and materials only.
- Observe all federal, state and local environmental regulations when discarding the product.
- In case of eye or skin contact with Vitrification/Thawing media, immediately flush eyes/skin with water.
- The user shall be responsible for any problems caused by non-conformity to the present IFU.
- Thawing media contain the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitive to this antibiotic.

**Note:** The long-term safety of the vitrification technique and maximum storage in liquid nitrogen has not been established and is unknown.

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