

# Ultra-Fast Warm

Code: VT602USUF-TSx4

March 16, 2026 Ver.2

## Intended Use

Ultra-Fast Warm is indicated for warming of previously vitrified oocytes (MI) and blastocyst stage embryos.

**Caution:** Sterile if the package is unopened or undamaged. Do not use it if the package is broken.

**Caution:** Federal law restricts this device to sale by or on the order of a physician or practitioner trained in its use.

## Warming Solutions

No.1 TS: 4 x 4.0ml vials

**Materials required but not included:**

• 35 mm dish or center-well dish for TS.

**Caution:** Use devices intended for its particular use. We recommend the use of Kitazato products in combination with this device.

## Instructions for Use (IFU)

**Preparation:**

• Warm TS vial (sealed) and an empty center-well dish in an incubator to 37 °C without CO2 (minimum 1.5 hours).

• Remove outer straw from the Cryotop® under liquid nitrogen.

**Caution:** The Cryotop® except its handle must remain immersed in liquid nitrogen at all time.

**Caution:** Make sure the tip of the Cryotop® does not touch liquid nitrogen.

## Warming

1. Once the TS vial and dish reached 37 °C and just before use, mix vial content and aseptically dispense 1–4 mL of TS into the dish. Quickly immerse the Cryotop® strip completely into the TS. Leave it for 1 minute.

2. Transfer the specimen to a culture dish containing the appropriate culture medium.

3. Incubate the specimen in a 37°C incubator to complete recovery.

**Caution 1:** It is recommended to incubate the specimens for minimum 2 hours after warming.

**Caution 2:** Wash and incubate the specimens for recovery in appropriate media to avoid the TS to be transferred to patient body.

## Quality Control Specification

Each lot of Ultra-Fast Warm receives the following tests:

- Sterility by the current USP Sterility Test <71>
  - Endotoxin by LAL methodology <0.25EU/mL(LAL)
  - Mouse Embryo Assay (1-cell to Blastocyst at 96h:≥80%)
  - pH (USP)
  - Osmolality (USP)
- MSDS and Certificate of Analysis available upon request and downloadable from our website (kitazato-ivf.com)

## Storage instructions and stability

Store the vials at 2-8 °C

Keep away from sunlight.

## Composition

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

















## Warnings

- Do not re-sterilize.
- Do not use solution that shows cloudiness or turned yellow for solution with phenol red.
- Do not use it if sterile packaging is broken.
- Ultra-Fast Warm must be stored in original unopened container, refrigerated at 2-8°C.
- To avoid contamination, do not reuse.
- Do not use after the expiration date.
- Aseptic techniques should be used.
- Currently, research literature indicates the long-term effects of vitrification on oocytes remains unknown.
- Product contains Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.

## Precautions

- Read the instructions for use prior to use.
- This product is intended to be used by only medical specialist of fertility treatment.
- Use sterilized equipment, materials and items.
- Decontaminate the workroom.
- Follow procedures in an environmentally controlled room.

## Symbol Glossary

|   |                              |   |   |
|---|------------------------------|---|---|
|  | Catalogue number             |    | Storage Temperature between 2-8°C                               |
|  | Batch code                   |    | Keep away from sunlight   |
|  | Medical device               |    | Do not use it if package is damaged                             |
|  | Unique Device Identifier     |    | Sterilized using aseptic processing techniques                  |
|  | Manufacturer                 |    | Single sterile barrier system                                   |
|  | Consult instructions for use |   | Single sterile barrier system with protective packaging outside |
|  | Prescription Only            |     | Use-by date   |
|  | Do not re-sterilize          |  | Date of manufacture   |

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