Ultra-Fast Vitri

Code: VT601USUF

July 03, 2025 Ver.1.0

Intended Use

Ultra-Fast Vitri is indicated for use in the preparation, vitrification, and storage of oocytes (MII).

Caution: The device is sterile as long as the package is unopened and undamaged. Do not use if the package is damaged .

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

Vitrification Solutions

- No. 1 (Color: Blue) – Equilibration Solution (ES): 1×1.5 ml vial or 1x4.0 ml vial.
- No. 2 (Color: Green) – Vitrification Solution (VS): 3×1.5 ml vials or 3×4.0 ml vials.

Caution: Before use, check the specifications of the container and labeling, including the number on top of the cap, cap color, vial labeling color, solution name, and volume. If you notice anything unusual regarding the items mentioned above, do not use the product and contact the distributor.

Caution: This product is sterilized. Handle it under aseptic conditions in a clean bench.

Materials Required but Not Included:

Below required products are supplied by Kitazato.

- Cryotop® SC/CL/US: 1 Cryotop® stores up to 4 Oocytes as a recommendation.
- Repro Plate or a standard dish
- Cooling Rack

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

Instructions for Use (IFU)

Preparation:

- Fill 90 % of the Cooling Rack with fresh liquid nitrogen.
- Bring ES and VS to room temperature.

Caution: Use a sterilized pipette, with a suitable internal diameter for oocytes or embryos. The recommended internal diameter is 120 µm for oocytes (MII).

A. Vitrification procedure using Repro Plate

Equilibration (1 min): 1. Dispense 300 µL of ES into first well on the Repro Plate using a pipette. **2.** Transfer the oocyte (MII) from the culture dish to the center top of the ES. It will sink and begin to shrink until the minimum volume is reached. This occurs in 1 minute.

Vitrification (1 min): Caution: Complete steps from 1 to 9 in 60 seconds. **1**. Dispense 300 µL of VS into second and third well of the Repro Plate using a pipette. **2.** Aspirate the specimen from ES with the tip of a pipette. **3**. Transfer the specimen to the center top of the VS1 of the second well. **4**. Aspirate the specimen with a pipette and blow it out. Repeat this process 3 times, changing the position in the VS1 of second well. **5**. Transfer the specimen to the bottom of the VS2 on the third well with a pipett e**6** Change the position of the specimen in the VS2 of third well with a pipette. **7**. Place the specimen near the black mark on the Cryotop® strip. **8.** Make sure the specimen is on the Cryotop® with a minimal volume of the VS (less than 0.1 µL) of third well under a microscope. **9**. Plunge the Cryotop® immediately in liquid nitrogen and shake it vigorously. **10**. Insert the Cryotop® in the outer straw and store it in a storage tank avoiding transferring it through the air at room temperature.

B. Vitrification procedure using standard dish

Equilibration (1 min): 1. Place oocyte(s) (up to four together) in a 50 µL drop of ES on a sterilized dish. It will begin to shrink until the minimum volume is reached. This occurs in 1 minute.

Vitrification: **Caution**: Complete steps from 1 to 6 in 60 seconds. **1.** Aspirate the specimen from ES drop with the tip of a pipette. **2.** Transfer the specimen into a single 50µL drop of VS1 for 30 seconds. **3.** Aspirate the specimen with a pipette and transfer it to a 50 µL drop of VS2 for 30 seconds. **4.** Place the specimen near the black mark on the Cryotop® strip. **5.** Make sure the specimen is on the Cryotop® with a minimal volume of VS (less than 0.1 µL) under a microscope. **6.** Plunge the Cryotop® mmediately in liquid nitrogen and shake it vigorously. **7.** Insert the Cryotop® in the outer straw and store it in a storage tank avoiding transferring it through the air at room temperature.

Caution : A larger volume may raise the risk of reducing cooling rate.

Note : The recommended load of the Cryotop® is up to 4 oocytes.

1. Cryotop® SC/CL: Place the Aluminum Block in Cooling Rack and fill 90% of Cooling Rack with fresh liquid nitrogen; allow the boiling to finish (about 5 minutes). Place the straw cap in the Aluminum Block and cut the upper mark band on the straw cap using the Straw Cutter.
2. Cryotop® SC/CL: Hold the straw cap with tweezers and insert the Cryotop®, making sure the tip does not touch the cap, holding up the Cryotop® SC/CL sheet within the 2.5cm height from the surface of liquid nitrogen. Seal the upper part of the straw cap with the sealer. Cryotop® US: Hold the straw cap with tweezers and insert the Cryotop® US, making sure the tip does not touch the cap. Fit the Cryotop® US with the cap by hand tightly.
3. Put the Cryotop® in a cane and store it in tank for long termstorage.

Caution : Take care that the Cryotop® remains immersed in liquid nitrogen at all times until thawing.

Quality Control Specification

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

- Sterility Test USP<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 ºC
Keep away from sunlight.

Composition

- HEPES within Basic Culture Medium
- Ethylene Glycol
- Dimethyl Sulfoxide
- 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 if sterile packaging is broken.
- Ultra-Fast Vitri must be stored in original unopened container, refrigerated at 2-8ºC.
- 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 or embryos 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 touse.
- This product is intended to be used by only medical specialist of fertility treatment.
- Use sterilized equipment, materials anditems.
- Decontaminate the workroom.
- Follow procedures in an environmentally controlled room.

Symbol Glossary

REF	Catalogue number
LOT	Batch code
MD	Medical device
UDI	Unique Device Identifier
	Manufacturer
	Consult instructions for use
Rx only	Prescription Only
	Do not resterilize
	Use-by date
8°C / 2°C	Storage Temperature between 2-8ºC
	Keep away from sunlight
	Do not use if package is damaged
STERILE A	Sterilized using aseptic processing techniques
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Do not reuse
	Date of manufacture

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