

■ Cryopreservation storage device for oocytes and embryos

Cryotop[®]US-flash

Cryotop[®]US-scoop

May 10, 2021 Ver.2

Indication for Use

Cryotop[®]US-flash and Cryotop[®]US-scoop are cryopreservation storage devices that are intended for use in vitrification procedures to contain and maintain human oocytes and embryos.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician.

Device Description

Cryotop[®]US-flash is a closed vitrification storage device composed of two parts: a shaft with a fine film tip for loading oocytes/embryos and an outer straw component for protection.

Cryotop[®]US-scoop is a closed vitrification storage device made by mold injection using medical grade polystyrene and composed of two parts; a shaft with a u-shaped fine film tip for loading oocytes/embryos and an outer straw component for protection.

Cooling Rate: 3,000 °C /min

Warming Rate: 44,000 °C /min

Equipment Needed

- Vitrification Media
- Thawing Media
- Culture Plate

Instructions for Use

Vitrification

1. Open the sterile pack of Cryotop[®]US-flash/Cryotop[®]US-scoop and identify patient information on the shaft handle of the device.
2. Fill 90% of a container with fresh liquid nitrogen.
3. Prepare oocytes or embryos for vitrification according to laboratory protocol.
4. Remove the cover straw from Cryotop[®]US-flash and Cryotop[®]US-scoop. Pre-cooling of the straw cover is not required.
5. After vitrification procedures, place the Cryotop[®]US-flash/ Cryotop[®]US-scoop under the microscope and adjust the focus on the black mark of the Cryotop[®]US-flash / Cryotop[®]US-scoop. The observed logo should be face-up.
6. Gently place oocytes or embryos on the tip of the Cryotop[®]US-flash/ Cryotop[®]US-scoop sheet with minimal volume ($\leq 0.1\mu\text{l}$) of vitrification media using a suitable pipette.

CAUTION: A larger volume of vitrification media on the Cryotop may reduce the cooling rate.

NOTE: The recommended load of the Cryotop[®]US-flash/ Cryotop[®]US-scoop are up to 4 oocytes or embryos.

7. Insert the Cryotop[®]US-flash /Cryotop[®]US-scoop into the straw cover. Make sure that the tip do not touch the edge of the straw cover and twist it tight.
8. Quickly plunge the Cryotop[®]US-flash /Cryotop[®]US-scoop into the prepared LN₂ container.
9. Put the Cryotop[®]US-flash/ Cryotop[®]US-scoop into the cane, then transfer it to the storage tank for long term storage.

CAUTION: Make sure that the Cryotop[®]US-flash / Cryotop[®]US-scoop must be kept in liquid nitrogen at all times until thawing.

Thawing

1. Thawing media should be prepared according to the Instructions for Use provided with the thawing media.
2. Identify Cryotop[®]US-flash /Cryotop[®]US-scoop to be warmed and check the patient information described on the shaft handle of the device.

NOTE : Keep the cover straw of Cryotop[®]US-flash /Cryotop[®]US-scoop immersed under the liquid nitrogen.

3. Hold the shaft handle of the device and remove the cover straw with the tweezers.

CAUTION: Make sure that the Cryotop[®]US-flash /Cryotop[®]US-scoop strip do not touch liquid nitrogen.

4. Quickly, within 1 second, immerse the tip of the Cryotop[®]US-flash/ Cryotop[®]US-scoop into the thawing media on the microscope stage.
5. Gently move the Cryotop[®]US-flash /Cryotop[®]US-scoop until oocytes/embryos are released from the tip.
6. Continue the thawing procedure according to the laboratory protocol.

Quality Control Specification

Each lot of Cryotop[®]US-flash and Cryotop[®]US-scoop tested for:

- Sterility by the current USP Sterility Test <71>
- Endotoxin by Photometric Techniques (<0.5EU/device)
- Mouse Embryo Assay (1-Cell to Blastocyst at 96h $\geq 80\%$)

Cryotop[®]US-flash and Cryotop[®]US-scoop are sterilized by gamma irradiation and validated to meet a sterility assurance level (SAL) of 10⁻⁶.

Storage Instructions and Stability

- Store in original sterile pack at 15-30 degrees Celsius.
- Cryotop[®]US-flash and Cryotop[®]US-scoop are stable until the expiration date shown on the package label when stored as directed.









Contraindication

- Do not re-use. This product is single use only.
- Do not re-sterilize.
- Do not use if the package is damaged.
- Observe all federal, state and local environmental regulations when discarding the product.
- Do not use if expiry date has been exceeded.

Warning

- Read the instructions for use prior to use.
- This product is intended to be used by only medical specialist of fertility treatment.
- Aseptic techniques should be used
- The product is sterile if the package is unopened or undamaged.
- Cryotop[®]US-flash and Cryotop[®]US-scoop should only be used in combination with vitrification media legally marketed in the United States for vitrification of oocytes and embryos.
- Liquid nitrogen may cause freeze burns if in contact with skin or eyes. Use appropriate precautions when working with liquid nitrogen.
- The long-term safety following vitrification procedures is unknown.

Symbols

	Sterilized using irradiation
	Do not Reuse
	Catalogue Number
	Batch Code
	Use by Date
	Storage Temperature
	Prescription Only
	Consult Instructions for Use

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