

Plate Instructions for Users

Device Description:

The Vitri and Warm Plates are designed for use in vitrification and warming procedures.
The Vitri and Warm Plates are provided sterile and consist of a lid and body incorporating three or four wells, respectively.
The Vitri and Warm Plates are manufactured from polystyrene.

Indications for use:

Vitri Plates are indicated for use in the preparation of human 4-8 cell and blastocyst stage embryos for vitrification.
Warm plates are indicated for use in the preparation and thawing of vitrified human 4-8 cell and blastocyst stage embryos.

Precautions:

Caution: Federal Law Restricts this device to sale by or on the order of a physical or practitioner trained in its use.
Do not use the product if the expiry date has been exceeded.
The long-term safety of children born following vitrification procedures is unknown
Do not use this product except for the intended use.
Do not modify this product for any reason.
Do not use the product if the sterile packaging is damaged or if the product is damaged or defective.
Avoid any damage caused by heavy physical impact or heavyweight objects.
When opening and using this product use aseptic technique to reduce the potential for contamination.
Discard this product in an appropriate manner in accordance with the regulations of your local authority.

Attention during Storage:

Plate: Store at 10-25 °C
Use before the expiration date indicated on the each of the labels.

Shelf-life:

2 years after the sterilized date.

Packaging:

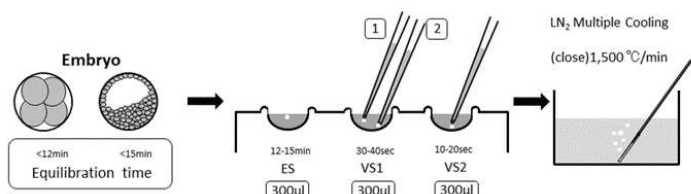
Primary package: OPP bag / Secondary package: OPP bag (for 10 pieces only)

Directions for Use:

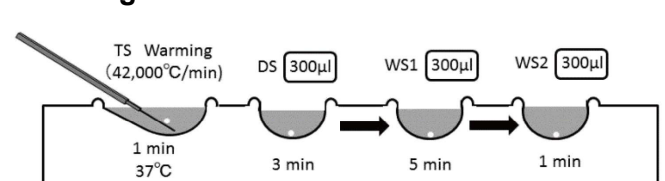
Vitri Plate: Open a bag and take the plate out. Put the plate on a microscope stage so that 3 wells come on the front side and a ditch for Cryotec comes on the back side. Remove the lid, and fill each well with solutions.

Warm Plate: Open a bag, take the plate out, keep a lid closed, and then place it inside the incubator at 37°C at least 3 hours before the use. Take the plate out from the incubator, and set it (a square well on the left side) on the microscope stage (align to the left at a right angle). Remove the lid, and fill each well with solutions.

Vitrification



Warming



*Cryotec: Vitrification storage device (FDA -approved)

*Solutions (ES, VS, TS, DS, WS): Solutions of Vitri/Warm kit manufactured by REPROLIFE Inc. (non-FDA-approved)

Specification:

Sterilization: Irradiation Sterilization (SAL10⁻⁶)
1-Cell MEA ≥80% developed to blastocyst within 96hrs.
Endotoxin < 0.5EU/device (LAL) (USP<85>)

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Table of Symbols (according to ISO 15223-1)















Symbol	Title	Description / Explanatory Text	Reference No. of Symbol
	Manufacturer	Indicates the medical device manufacturer	5.5.1
	Date of Manufacture	Indicates the date when medical device was manufactured	5.1.3
	Use by Date	Indicates the date after which device is not to be used	5.1.4
	Batch Code	Indicates the manufacturer's batch code so that the lot or batch can be identified	5.1.5
	Catalogue Number	Indicates the manufacturer's catalogue number, to identify the medical device	5.1.6
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	5.2.4
	Do Not Resterilize	Indicates a medical device that is not to be resterilized	5.2.6
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened	5.2.8
	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources	5.3.2
	Keep Dry	Indicates a medical device that needs protection from moisture	5.3.4
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed	5.3.7
	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	5.4.2
	Consult Instructions for Use	Indicates the need for user to consult the instructions for use	5.4.3

Table of Abbreviation

	Prescription use only	Caution: Federal Law Restricts this device to sale by or on the order of a physical or practitioner trained in its use.	21 CFR 801.109
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IFU-000803, 06/02/2023 Rx Only