

# Plastic Ware for ART

Ver.3

## Vitrification/thawing Plate

### Indication for Use

Repro Plate is the plate used for holding the solution/media that perform vitrification/thawing of Oocytes or Embryos during Assisted Reproductive Technology (ART).

### Instructions for Use

#### ■Preparation

- Prepare the device and instruments needed for laboratory's procedures and protocols.
- Write necessary information about the patient on the lid/base (main body) of Plate/Dish.

#### ■Instructions for use

1. Put vitrification/thawing medium on Plate/Dish based on laboratory's procedures and protocols.
2. Transfer Oocytes or Embryos to the vitrification/thawing medium, and then manipulate them according to the laboratory's procedures and protocols.

**Note:** For vitrification and thawing process, follow the protocol of the KITAZATO product.

**Caution:** The detailed usage of Repro Plate is determined based on each laboratory's procedures and protocols that are optimized for individual medical purposes.

## Culture Dish

### Indication for Use

Culture Dish is the dish used for holding the solution/media that cultures Oocytes or Embryos during ART.

### Instructions for Use

#### ■Preparation











- Prepare the device and instruments needed for laboratory's procedures and protocols.
- Write necessary information about the patient on the lid/base of Dish.

#### ■Instructions for use

1. Put culture medium on Dish based on laboratory's procedures and protocols.
2. Transfer Oocytes or Embryos to the culture medium, and then manipulate them according to the laboratory's procedures and protocols.

**Caution:** The detailed usage of Dish is determined based on each laboratory's procedures and protocols that are optimized for individual medical purposes.

### Quality Control Specification

	Sterilized Using Irradiation
	Do not reuse
	Catalogue number
	Batch code
	Use by
	Storage temperature
	CE mark
	Manufacturer
	Do not re-sterilize
	Do not use if package is damaged
	Consult instructions for use
	Keep away from sunlight
	Authorized representative in the European Community

### Quality Control Specification

Each lot ensures the following.

- Endotoxin by Photometric Techniques(LAL):  $\leq 0.5$ EU/device
- Mouse Embryo Assay (one cell) :  $\geq 80\%$
- Sterilized by gamma irradiation and validated to meet sterility assurance level (SAL):  $10^{-6}$

### Storage instructions, Warnings and stability

- Store at 15 to 30 °C.
- This product is sterile until the expiry date showed on the label if the package or container is unopened or undamaged.
- Keep away from sunlight.

### Contraindications

- To avoid deterioration, do not re-sterilize.
- To avoid contamination, do not re-use.
- Do not use if the package or container are opened or damaged.
- Do not use the product after expiration date or infected product or used product, and discard it (see the warning).
- This product is intended to be used by medical specialists trained in fertility treatment.

### Warnings

- Read the instructions for use prior to use.
- Aseptic technique should be used.
- Use sterilized equipment and materials only.
- In case of infection or used product, dispose the product appropriately in a prescribed manner.
- The user shall be responsible for any problems caused by non-conformity to the present IFU.
- Observe all federal, state and local environmental regulations when discarding the product.

**NOTE:** Single use device. Lifetime of the device is determined by applied Assisted Reproductive Techniques and is maximum to the period of embryo culture.

**KITAZATO**®



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