



Instructions for the Use of the μ Drop GPS[®] Dish

(Catalogue Number: MGPS-010)

PRECAUTIONS AND WARNINGS

1. **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
2. **Caution:** The user should read and understand the Instructions for Use, Precautions and Warnings, and be trained in the correct procedure before using the μ Drop GPS[®] Dish.
3. Do not use the product if the product packaging appears damaged or broken.
4. For single use only. Do not use after expiry date.
5. To avoid problems with contamination, practice aseptic techniques.

GENERAL INFORMATION

Indications for Use

The μ Drop GPS[®] micro-wells dish is specifically designed for oocyte and embryo handling and culture. The sloped concave micro-well bottoms of the μ Drop GPS[®] dish allow oocytes and embryos to settle at a central location away from the well walls. The outer wells are intended for holding media or oil. The concave nature of the wells provides the thinnest well bottom possible, helping to reduce refraction and allow for optimal visualization. The wells may reduce droplet collapsing/mixing, offer better orientation/optics, and reduce set-up/observation time.

Storage and Shelf Life

Store at room temperature.

Composition

The μ Drop GPS[®] dish is constructed of polystyrene and is non-pyrogenic. It has passed USP class VI testing and is sterilized by gamma irradiation.

QUALITY CONTROL SPECIFICATIONS

Parameter	Specification
LAL Endotoxin	< 20 EU/device
1-cell Mouse Embryo Assay (% blastocysts at 96 h of culture)	\geq 80%

INSTRUCTIONS FOR USE

The procedures described below have been found to be effective for the handling and culture of human oocytes and embryos in the μ Drop GPS[®] dish. Every laboratory must define and optimize its own procedures.

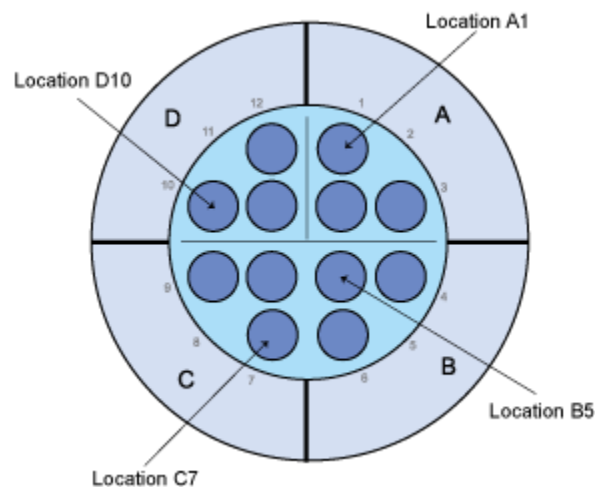
Off-gassing the μ Drop GPS[®] dish

μ Drop GPS[®] dish packages may be off-gassed with the sleeve partially opened or the dishes may be removed entirely from the packaging. In either case, the opened sleeves, or dishes, must be kept in a sterile environment at ambient temperature. The dishes should remain covered with the lids until they are loaded with the culture medium and oil.

Marking the μ Drop GPS[®] Dish for Embryo and Patient Identification

Patient identification can be writing using a waterproof non-toxic or diamond pen in the outer bottom side of the dish. There is a marker at the 12 o'clock position designed to assist the user in orientation of the wells. For embryo/oocyte identification, the μ Drop GPS[®] dish has a series of letters and numbers moulded into each quadrant. Each quadrant is marked with a letter (A-D) and each micro-well is marked with a number (1-12). These alphanumeric markers can be used for embryo identification and monitoring of embryo development (see **Figure 1**).

Figure 1. Example alphanumeric locations found on the μ Drop GPS[®] dish. See text for complete instructions.



Oil Preparation

Ensure that the oil is thoroughly washed and quality control tested prior to its use in embryo culture.

Pipetting Culture Media and Oil into the μ Drop GPS[®] Dish

There are two approaches to pipetting culture media and oil into the μ Drop GPS[®] dish. An oil-overlay technique may be used in which the culture medium is first pipetted into the wells and then covered with oil. Alternatively, an oil-underlay technique may be used in which the dish is first filled with oil and then the culture medium is under-laid into the culture wells.

Preparation of μ Drop GPS[®] dish for IVF should be done in a laminar flow cabinet using appropriate sterile techniques. Use a non-heated surface area to minimize evaporation.

A. Oil-overlay Technique

- Carefully pipette 20 μ l of culture medium into each of the inner micro-wells, and up to 1 mL of culture medium or oil into each of the outer wells. Be careful not to touch the bottoms of the wells with the pipette in order to prevent scratches and or release of plastic debris into the medium.
- Pipette 3 ml of oil into the in the central well covering the micro-wells, using a location away from the wells to gently distribute the oil overlaying the wells previously filled with culture medium.

B. Oil-underlay Technique

- Pipette 3 ml of oil into the central well covering the micro-wells.








2. Through the oil, carefully pipette 20 µl of culture medium into each of the inner micro-wells and up to 1 mL of culture medium into each of the outer wells. Be careful not to touch the bottoms of the wells with the pipette in order to prevent scratches and or release of plastic debris into the medium.

Pipetting Oocytes and Embryos into the into the µDrop GPS® Dish

The GPS designed well bottoms have a gently sloping concave bottom which results in the oocytes and embryos migrating towards a central location by gravity. This is generally accomplished within a few minutes as the oocytes and embryos settle after a dish is moved or handled. This feature helps promote rapid visualization of the oocyte or embryo.

Oocytes and embryos may be pipetted in and out of the wells of the µDrop GPS® dish using any type of pipetting device or technique commonly used in the IVF laboratory; however, care should be taken not to scratch the well bottoms during pipetting. Generating plastic debris from scratches may adhere to eggs or embryos and scratches may hinder visualization.

SYMBOLS

<div style="border: 1px solid black; padding: 2px; display: inline-block;">STERILE R</div>		<div style="border: 1px solid black; padding: 2px; display: inline-block;">REF</div>	<div style="border: 1px solid black; padding: 2px; display: inline-block;">LOT</div>		
Sterilize By Irradiation	Do Not Reuse	Catalogue Number	Batch Code	Consult Instructions For Use	Manufacturer
		<div style="border: 1px solid black; padding: 2px; display: inline-block;">EC REP</div>			
Keep Dry	Do Not Use if Package is Damaged	Authorized Representative in the European Community	Use By	European Conformance (notified body)	