



Instructions for the Use of the 4-Well GPS® Dish

(Catalogue Number: 4GPS-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 4-Well 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 4-Well GPS® dish is specifically designed for oocyte and embryo handling and culture. The four (4) outer wells are intended for washing and holding oocytes and embryos. The four (4) inner wells are intended for larger-volume embryo and oocyte culture and handling. The wells found in the 4-Well GPS® dish are concave which causes oocytes and embryos to settle at a central location away from the well walls. 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 4-Well 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)	≥ 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 4-Well GPS® dish. Every laboratory must define and optimize its own procedures.

Off-gassing the 4-Well GPS® dish

4-Well 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 and humidity. The dishes should remain covered with the lids until they are loaded with the culture medium and oil.

Marking the 4-Well GPS® Dish for Embryo and Patient Identification

Patient identification can be writing using a waterproof non-toxic or diamond pen in the area below the central wells of the 4-Well GPS® dish.

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 into the 4-Well GPS® Dish

There are two approaches to pipetting culture media and oil into the 4-Well 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 4-Well 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.

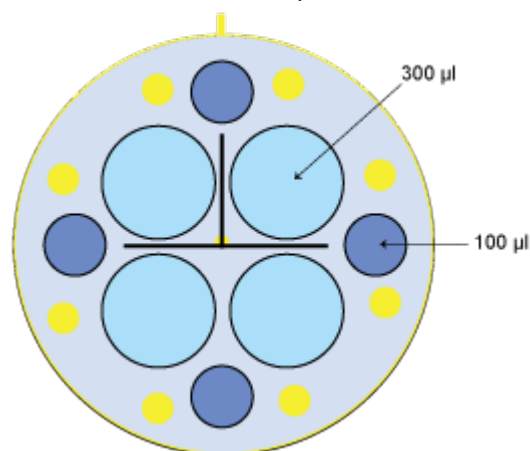
A. Oil-overlay Technique

1. Carefully pipette up to 100 μ l of culture medium into each of the outer wells, and up to 300 μ l of culture medium into each of the inner 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.
2. Pipette 12 ml of oil into the dish using a location away from the wells to gently distribute the oil overlaying the wells previously filled with culture medium.

B. Oil-underlay Technique

1. Pipette 12 ml of oil into the dish.
2. Through the oil, carefully pipette up to 100 μ l of culture medium into each of the outer wells, and up to 300 μ l of culture medium into each of the inner 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.

Figure 1. Volumes of medium required for 4-Well GPS® dish.














Pipetting Oocytes and Embryos into the into the 4-Well 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 4-Well 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

					
Sterilize By Irradiation	Do Not Reuse	Catalogue Number	Batch Code	Consult Instructions For Use	Manufacturer
					
Keep Dry	Do Not Use if Package is Damaged	Authorized Representative in the European Community	Use By	European Conformance (notified body)	