



Instructions for the Use of the 38Special GPS® Dish

(Catalogue Number: SP38-010)

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 38Special 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 38Special GPS® micro-wells dish is specifically designed for oocyte and embryo handling and culture. This 38mm dish replicates the 60 mm μ Drop GPS® dish but uses a suspended well design. The suspended round wells use a well bottom with an increased slope to enhance their GPS function. The sloped concave micro-well bottoms of the 38Special GPS® dish allow oocytes and embryos to settle at a central location away from the well walls. The dish is a 12 round well pattern in 4 rows. Two large triangle shaped wells are closer to the dishes exterior vertical walls. The triangle wells are by design recommended for washing oocytes and embryos. 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 38Special 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 38Special GPS® dish. Every laboratory must define and optimize its own procedures.

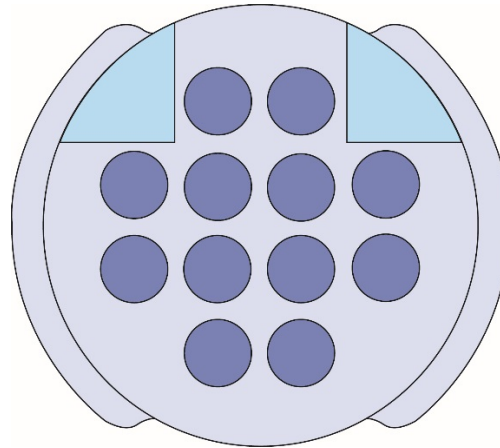
Off-gassing the 38Special GPS® dish

38Special 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 38Special GPS® Dish for Embryo and Patient Identification

Patient identification can be writing using a waterproof non-toxic or diamond pen on the outer side of the dish. Alternatively, a label can be placed at the bottom of the dish over some of the drops. (see **Figure 1**).

Figure 1. Example of the 38Special 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 38Special GPS® Dish

There are two approaches to pipetting culture media and oil into the 38Special 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 38Special 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 60 μ l of culture medium into each of the triangle 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 4 ml of oil into 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 4 ml of oil into the central well covering the micro-wells.
- Through the oil, carefully pipette 20 μ l of culture medium into each of the inner micro-wells and 60 μ l of culture medium into each of the triangle 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 38Special GPS® Dish

The 38Special GPS® dish 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 38Special 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)	GS1 DataMatrix Barcode