



Instructions for the Use of the embryo corral® Dish

(Catalogue Number: EMBC-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 embryo corral® 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 embryo corral® dish is an advanced culture dish designed for IVF that allows group culture of embryos while maintaining individual separation between the embryos.

The embryo corral® dish has eight (8) outer wells designed for efficient oocyte, embryo handling and culture. The gently sloped concave well bottoms allow 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.

The embryo corral® dish has two (2) central wells designed to take advantage of the potential benefits of group embryo culture. Each embryo corral® dish central well is divided into four quadrants. The quadrants are separated by posts to permit media exchange between quadrants without allowing movement of embryos. The oil-media interface acts as a cap for the quadrants to create the individual permeable culture wells. The embryo corral® quadrants have more steeply sloped bottoms to enhance embryo location and aid pipetting in these smaller individual culture wells (quadrants).

Storage and Shelf Life

Store at room temperature.

Composition

The embryo corral® 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 embryo corral® dish. Every laboratory must define and optimize its own procedures.

Off-gassing the embryo corral® dish

Embryo corral® 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 embryo corral® 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 embryo corral® dish. There is a marker at the 12 o'clock position designed to assist the user in orientation of the wells.

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 embryo corral® Dish

An oil-overlay technique is the only method recommended for use with the embryo corral® dish central culture wells. The culture media is first pipetted into the wells and then covered with oil. The oil-underlay technique is not recommended for use with the embryo corral® dish since the oil may clog the narrow openings between the quadrant posts. Under laying the media may not be effective at displacing the overlaid oil from these narrow post openings, reducing the potential benefits of group embryo culture.












Pipette 50 µl of culture medium into each of the eight (8) outer wells, and 30 µl of culture medium into each of the eight (8) inner quadrant Wells (120 µl for each inner well). Pipette 12 ml of oil into the dish overlaying the wells previously filled with culture medium.

Pipetting Oocytes and Embryos into the into the embryo corral® 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 can be pipetted in and out of the wells of the embryo corral® dish using any type of pipetting device or technique commonly used in the IVF laboratory. 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)	