

0258-01

EmbryoGen®

Product No.:

1204

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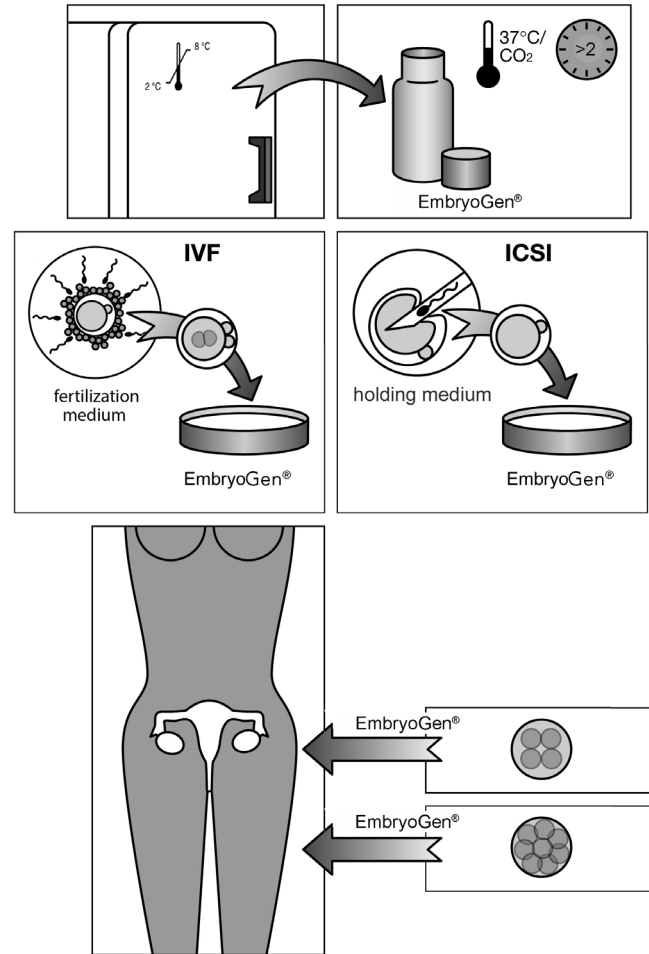
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origio

a CooperSurgical Company



EmbryoGen®

Indication for use

EmbryoGen® is for culture of human embryos until the 2-8 cell stage.

EmbryoGen® can also be used for embryo transfer at day 2 or 3.

Composition

Leukine (sargramostim) GM-CSF 2 ng/mL

Human serum albumin (HSA) 5 mg/mL

Gentamicin sulphate 10 µg/mL

Glucose

Sodium pyruvate

Calcium lactate

Physiological salts

Amino acids

L-glutamine (stable form)

Vitamins

EDTA

Sodium hyaluronate

Sodium bicarbonate

Quality control testing

Leukine (sargramostim) GM-CSF

concentration (ELISA) and potency (TF-1 bioassay)

Sterility tested (Ph.Eur., USP)

Osmolality tested 272-288 mOsm/kg (Ph.Eur., USP)

pH tested 7.2-7.4 (Ph.Eur., USP)

Endotoxin tested < 0.15 EU/mL (Ph.Eur., USP)

1-cell Mouse Embryo Assay (MEA) ≥ 80% blastocysts by 96h

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability

Store in original container at 2-8°C, protected from light.

Do not freeze.

Discard excess (unused) media following warming.

The product is to be used within 7 days after opening.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Precautions and warnings

Do not use the product if:

1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician (Rx only).

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product was tested and found non-reactive for HBsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV.

Furthermore source material has been tested for parvovirus B19 and found to be non elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Instructions for use

1. Equilibrate for a minimum of 2 hours in 5-6% CO₂ at 37°C prior to use. The time required to achieve full equilibration depends on volume of medium and oil overlay.
2. For IVF cases, fertilize in ORIGIO® Sequential Fert™ or preferred fertilization medium. Transfer zygotes from the fertilization medium to drops or wells of pre-equilibrated EmbryoGen® and return the dish to the incubator.
3. For ICSI cases, transfer oocytes from the holding medium to drops or wells of pre-equilibrated EmbryoGen® immediately after sperm injection and return the dish to the incubator.

Embryo transfer

1. The embryos are prepared and transferred to the uterus on day 2 or 3 in 20 to 30 µl of pre-equilibrated EmbryoGen®.
2. Flush the transfer catheter with EmbryoGen® or other protein containing transfer medium prior to use.