

ORIGIO® Sequential Fert™

Product No.:

8301

8302

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ORIGIO a/s

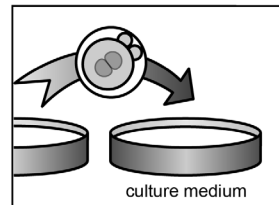
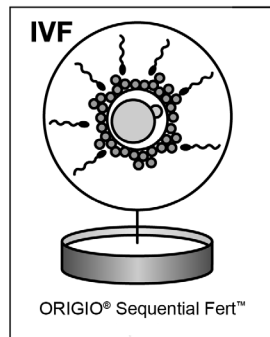
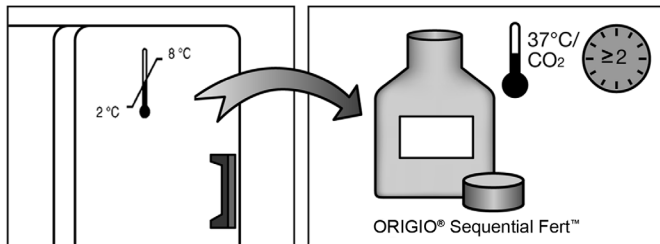
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a CooperSurgical Company



ORIGIO® Sequential Fert™

Indication for use

ORIGIO® Sequential Fert™ is for the fertilization of oocytes in vitro.

Composition

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 bicarbonate
Phenol red (only product no.8302).

Quality control testing

Sterility tested (Ph.Eur., USP)
Osmolality tested 277-293 mOsm/kg (Ph.Eur., USP)
pH tested 7.3-7.5 (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.
The product is to be used within 7 days after opening.
Discard excess (unused) media following warming.
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 ORIGIO® Sequential Fert™ 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. Recover oocytes as usual and prepare sperm according to preferred procedure.
3. Carry out fertilization, either conventional IVF or Intracytoplasmic Sperm Injection (ICSI), in pre-equilibrated ORIGIO® Sequential Fert™. It is recommended that this be done in either microdrops or wells using the laboratory's preferred final sperm concentration.
For pH control outside of the incubator, ICSI may be performed in a HEPES-buffered holding medium, in place of ORIGIO® Sequential Fert™.
It is recommended that zygotes are transferred from ORIGIO® Sequential Fert™ to pre-equilibrated cleavage medium immediately after ICSI.
4. At 16-20 hours post insemination, check for formation of pronuclei, then carefully wash and transfer zygotes to fresh drops or wells of pre-equilibrated culture medium.

It should be determined within individual laboratories as to which medium best suits which procedure.