

ORIGIO® Sequential Fert™

Product No.:

8301

8302

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Explanation of Symbols (in random order)



Use within 7 days of opening



Do not use if package is damaged



Discard excess (unused) media following warming



Indicates the medical device manufacturer



Indicates the manufacturer's batch code so that the batch or lot can be identified



Indicates the date after which the medical device is not to be used



Indicates the manufacturer's catalogue number so that the medical device can be identified



Indicates a medical device that has been manufactured using accepted aseptic techniques



Indicates a medical device that needs protection from light sources



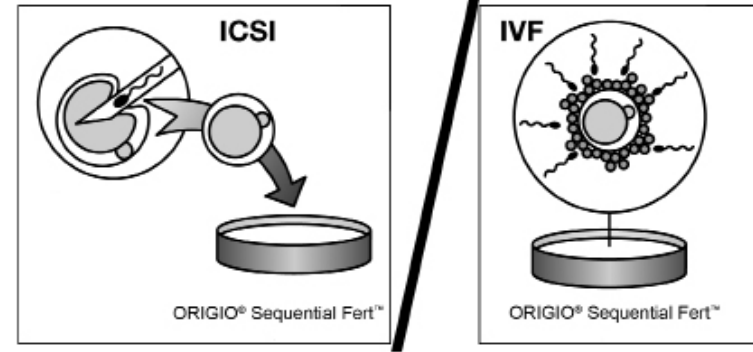
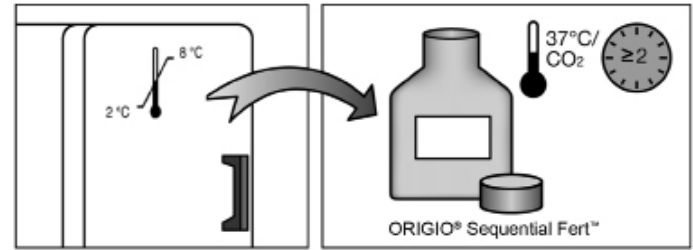
Indicates the need for the user to consult the instructions for use



Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions



Indicates the temperature limits to which the medical device can be safely exposed



ORIGIO® Sequential Fert™

For fertilisation of oocytes by conventional in vitro fertilisation (IVF) or Intracytoplasmic Sperm Injection (ICSI).

This product is for ART treatment, whether the cause of infertility is male or female. The product should only be used by professionals trained in ART treatment.

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 (Ph.Eur., USP)
pH tested (Ph.Eur., USP)
Endotoxin tested ≤ 0.1 EU/ml (Ph.Eur., USP)
1 cell Mouse Embryo Assay (MEA) $\geq 80\%$
Blastocysts by 96h

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

Storage instructions and stability

The products are aseptically processed and supplied sterile.
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 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: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of ART media has not been determined and is still unknown.

Note: Dispose of the device in accordance with local regulations for disposal of medical devices.

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. Recover oocytes as usual and prepare sperm according to preferred procedure.
3. Carry out fertilization, either conventional IVF or ICSI, in pre-equilibrated ORIGIO® Sequential Fert™. *As ORIGIO® Sequential Fert™ requires CO₂ equilibration, ICSI may also be performed in a HEPES-buffered holding medium.*
It is recommended that zygotes are transferred to pre-equilibrated culture medium immediately after ICSI.
4. At 16-20 hours post insemination, check for formation of pronuclei, then carefully wash and transfer zygotes to fresh microdrops or wells of pre-equilibrated culture medium.

Each laboratory should make its own determination of which medium to use for each particular procedure.