

ORIGIO® Sequential Cleav™

Product No.:

8303

8304

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ORIGIO a/s

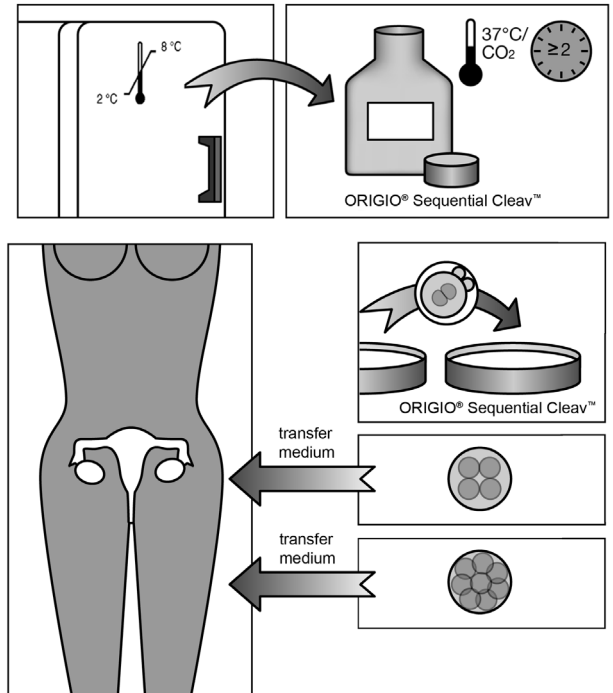
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a CooperSurgical Company



ORIGIO® Sequential Cleav™

Indication for use

ORIGIO® Sequential Cleav™ is for the culture of embryos until the 2-8 cell stage. ORIGIO® Sequential Cleav™ can also be used for embryo transfer at day 2 or 3.

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 hyaluronate
Sodium bicarbonate
Phenol red (only product no.8304)

Quality control testing

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.
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 Cleav™ 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. Transfer zygotes from the fertilization medium to fresh drops or wells of pre-equilibrated ORIGIO® Sequential Cleav™ and return the dish to the incubator.

Embryo transfer

1. The embryos are prepared and transferred to the uterus in 20 to 30 µl of pre-equilibrated fresh ORIGIO® Sequential Cleav™ or preferred transfer medium.
2. Flush the transfer catheter with the chosen transfer medium prior to use

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