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ORIGIO® Handling™

Product No.:
8310
8311

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a CooperSurgical Company

ORIGIO® Handling™

Indication for use
ORIGIO® Handling™ is intended for *in vitro* procedures involving handling and micromanipulation of gametes and embryos outside the CO_2 incubator.

Indication includes oocyte retrieval including follicle flushing, gamete (oocyte/sperm) and embryo washing, and micromanipulation procedures including Intra Cytoplasmic Sperm Injection (ICSI), assisted hatching and trophectoderm biopsy.

Pack size

83100060D	ORIGIO® Handling™ (60 ml)
83100125D	ORIGIO® Handling™ (125 ml)
83110060D	ORIGIO® Handling™ with phenol red (60 ml)
83110125D	ORIGIO® Handling™ with phenol red (125 ml)

Composition
Human Serum Albumin (HSA) 5 mg/mL
Gentamicin sulphate 10 µg/mL
Amino acids
L-Alanyl-L-glutamine
Vitamins
Glucose
Sodium pyruvate
Calcium L-lactate
Physiological salts
Sodium bicarbonate
HEPES sodium salt
MOPS Free acid
Phenol red (only product 8311)

Quality control testing
Sterility tested (Ph.Eur., USP<71>)
Osmolality tested 277-293 (Ph.Eur., USP<785>)
pH tested 7.30-7.50 (Ph.Eur., USP<791>)
Endotoxin tested ≤ 0.1 EU/mL (Ph.Eur., USP<85>)
1-cell MEA: ≥80% blastocysts at 96h
Human Sperm Survival Assay (HSSA): Sperm Motility ≥80% of control after incubation for 6 hours
Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Buffer system
ORIGIO® Handling™ uses a buffering system composed of a HEPES, MOPS and sodium bicarbonate combination. This buffering system provides a physiological pH of 7.4 at 37°C and does not require the use of a CO_2 incubator.

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.
3. The product becomes discoloured, cloudy, turbid, or shows any evidence of microbial contamination.

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.

Caution: Oocytes are extremely sensitive to pH changes, transient cooling and warming *in vitro*. Modest fluctuations in temperature can cause disruption of the meiotic spindle with possible chromosome dispersal.

Caution: This product contains Gentamicin and should not be used on patients that have known allergy to Gentamicin or similar antibiotics.

Note: Please note the need for traceability of this product. In addition national legal requirements in your country may exist in this field.

Note: Only to be used in combination with other devices intended for the particular purpose.

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

Instructions for use

1. Pre-warm ORIGIO® Handling™ to 37°C prior to use, except for sperm washing where ORIGIO® Handling™ is pre-warmed to room temperature prior to use (20-25°C).
   Note: make sure the bottle is tightly capped during warming.
2. During those procedures required to be performed at 37°C, steps must be taken to ensure that the temperature remains at 37°C at all times.
3. Flush syringes, pipettes etc. with pre-warmed ORIGIO® Handling™ before use.

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

Trophectoderm Biopsy – Directions for use

1. **Preparation of dish**

- **Culture dish.** Place droplets of culture media into a sterile culture dish and add 2 droplets for washing, immediately cover with preheated oil and place the dish in the CO2 incubator for equilibration.
- **Biopsy dish.** Place an appropriate number of droplets of ORIGIO® Handling™ into a sterile biopsy dish. Make one droplet per blastocyst to be biopsied. Immediately cover the droplets with pre-heated oil. Place the dish on a heated stage or in an incubator without CO_2 at 37°C.

2. Take the pre-warmed biopsy dish and transfer the blastocyst into the middle of the droplet in the dish.
3. **Biopsy procedure.** Perform the biopsy procedure according to laboratory protocol in order to obtain biopsied cells.

- Rinse the biopsied blastocyst in the wash droplets and place it into the culture droplet of the pre-equilibrated culture dish.
- Deposit the biopsied cells into a separate biopsy droplet.
- Repeat until all blastocysts have been biopsied.
- Leave the biopsied cells in the droplets of the biopsy dishes until all blastocysts have been biopsied.
- After all blastocysts have been biopsied, the biopsy dishes with the isolated cell samples are then ready for sample preparation according to the instructions of the molecular diagnostic center.

Sperm washing - Direction for use

1. Allow the ORIGIO® Handling™ to reach room temperature.
2. Allow the semen to liquefy at room temperature. Using aseptic technique, transfer the liquefied semen into a sterile conical centrifuge tube and add ORIGIO® Handling™ at room temperature.
3. Centrifuge the tube at ambient temperature for 10 minutes at 200 – 300 g.
4. Using a sterile Pasteur pipette, remove and discard the supernatant above the sperm pellet by aspiration. The sperm should then be resuspended by gently flicking the tube externally with the index finger. Re-suspend the sperm in fresh medium, recap and gently mix by inversion. Centrifuge as in step 3.
5. Using a sterile Pasteur pipette, remove and discard the supernatant and re-suspend the sperm pellet gently by manual agitation. Add fresh medium to the desired volume. The spermatozoa are ready for assisted reproductive procedures.

Processing the high viscous semen sample:

1. After step 2 in the sperm washing procedure, aspirate and expel the mixture gently using an 18 gauge or 19 gauge needle and syringe.
2. Limit the amount of medium-sperm mixture from 1 to 5 ml per centrifuge tube for the first centrifuge step.
3. If, after preprocessing the sample with the needle and syringe, the sperm do not "pellet" in a normal manner, carefully aspirate as much of the supernatant as possible without disrupting the "cloudy sperm fiber" using a sterile needle and syringe. Next, add 2 or 3 ml fresh medium. Repeat the process of drawing the mixture through the needle and syringe. Re-centrifuge the mixture. The sperm should pellet normally after the second processing.