0260-03

Instructions for Use

ORIGIO® Gradient™ 90

Product No.:
8401

Customer Service:
E-mail: sales@coopersurgical.com

ORIGIO a/s
Knardrupvej 2, 2760 Måløv, Denmark
www.fertility.coopersurgical.com
Tel: +45 46 79 02 00

a CooperSurgical Company

ORIGIO® Gradient™ 90

For the separation of motile sperm from the ejaculate by the density gradient method.

Pack size
84010060D ORIGIO® Gradient™ 90 (60 ml)

Composition
Gentamicin sulphate 10 µg/ml
Human Serum albumin (HSA)
Glucose
Sodium pyruvate
Physiological salts
Taurine
Silane-coated silica particles
HEPES
Sodium bicarbonate

Quality control testing
Sterility tested (Ph.Eur., USP)
Osmolality tested 297-313 mOsm/kg (Ph. Eur., USP)
pH tested 8.0-8.5 (Ph.Eur., USP)
Endotoxin tested ≤0.8 EU/ml (Ph.Eur., USP)
Sperm survival tested motility ≥80% of control
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
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 28 days after opening.
When stored as directed by the manufacturer the product is stable until the expiry date shown on the label.

Buffer system
ORIGIO® Gradient™ 90 is a fully HEPES buffered medium and does not require pre-incubation before use

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.

Note: Please be aware that precipitation (colloidal aggregates) may occur. Decanting the medium is recommended when precipitation is present

Instructions for use
For custom gradient preparation use below chart to prepare a 45 % upper phase solution using the ORIGIO® Gradient™ 90 and ORIGIO® Sperm Wash.

ORIGIO® Gradient™ 90	ORIGIO® Sperm Wash	End result
5 ml	5 ml	**= 10 ml upper phase 45% solution**

1. Bring all components to room temperature (20-25°C) before use.
2. For each 1-2ml of semen sample used, prepare a separate gradient using 1-2 ml of the upper phase custom made 45% solution carefully underlain with 1-2 ml of lower phase ORIGIO® Gradient™ 90

   Optimal results may be achieved if gradients are prepared shortly before use.
3. Carefully dispense 1-2 ml of liquefied semen sample on top of the prepared gradient.
   Care should be taken not to overload the gradient as this may result in a poor sperm yield.
4. The gradient is centrifuged at 300-400 g for

15-20 minutes.
Centrifugation speed and duration may be modified to improve the quality and/or yield of sperm collected, depending on the initial semen characteristics.

5. Remove the supernatant from the pellet and transfer the pellet with a new sterile tip into a clean conical centrifuge test tube containing 3-5 ml of ORIGIO® Sperm Wash.
6. Centrifuge at 200-300g for 5-10 minuts. Aspirate and remove most of the supernatant.
   Repeat this washing procedure.
7. Finally re-suspend the pellet in appropriate medium according to further procedure; determine the motility and concentration of spermatozoa.
8. If needed, further dilute the re-suspended sperm pellet to obtain the required sperm concentration.

Note: For IVF procedures it is advised to use a specialized fertilization medium (e.g. ORIGIO® Sequential Fert™) when re-suspending the pellet (step 7/8). For ICSI procedures where no immobilization medium (e.g. PVP, SpermSlow™) is used for sperm selection, it is advised to use an alternative holding medium when re-suspending the pellet (step 7/8)

Note: Prolonged storage of re-suspended sperm pellets before use, no matter the media used, may increase the sperm DNA fragmentation index, especially in male factor infertility cases [1, 2]

[1] Jackson R.E, et al., Effects of semen storage and separation techniques on sperm DNA fragmentation. Fertil Steril. 2010;94(7):2626–2630.

[2] Balasuria A, et al., Processes involved in assisted reproduction technologies significantly increase sperm DNA fragmentation and phosphatidylserine translocation. Andrologia. 2014 Mar; 46(2):86-97