

Instructions for Use

ORIGIO® Sperm Wash

Product No.:

8405

Customer Service:

E-mail:

customer.service@origio.com

Tel: +45 46 79 02 02 • Fax: +45 46 79 03 02

ORIGIO a/s

Knardrupvej 2, DK-2760 Måløv, Denmark

www.origio.com

Tel: +45 46 79 02 00 • Fax: +45 46 79 03 00



a CooperSurgical Company

ORIGIO® Sperm Wash

For washing of spermatozoa, the isolation of motile viable sperm by swim-up method, dilution of ORIGIO® Gradients™, and holding sperm for IUI procedure.

Pack size

84050010D	ORIGIO® Sperm Wash (10 ml)
84051010D	ORIGIO® Sperm Wash (10x10 ml)
84050060D	ORIGIO® Sperm Wash (60 ml)
84055060D	ORIGIO® Sperm Wash (5x60 ml)

Composition

Gentamicin sulphate 10 µg/ml

Human Serum albumin (HSA)

Glucose

Sodium pyruvate

Physiological salts

Taurine

HEPES

Sodium bicarbonate

Quality control testing

Sterility tested (Ph.Eur., USP)

Osmolality tested 272-288 mOsm/kg (Ph.Eur., USP)

pH tested 8.0-8.5 (Ph.Eur., USP)

Endotoxin tested < 0.15 EU/ml (Ph.Eur., USP)

HSA analysis (Ph.Eur., USP)

Sperm survival tested

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

Buffer system

ORIGIO® Sperm Wash is a fully HEPES

buffered medium and does not require pre-incubation before use.

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.

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.

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

Instructions for use

Swim Up preparation:

1. Bring all components to room temperature (20-25°C) before use.
2. Carefully layer 0.5-1 ml of the liquefied semen in a tube underneath 1-2 ml ORIGIO® Sperm Wash.
3. If possible, place the tube at a 30-45° angle to increase the interface between the semen sample and the ORIGIO® Sperm Wash. This is done in order to increase recovery of the most motile spermatozoa as they migrate into the medium. Place the rack in an incubator at 37°C for 30-60 minutes depending on the semen quality. If a CO₂ incubator is used make sure the tubes are tightly capped.
Note: The swim-up can also be performed at room temperature.
4. After swim-up the upper 0.2-1 ml is aspirated and assessed for sperm concentration and motility. If the sperm count is too low, the next 0.5 ml is included as well. Pool the aspirates together. *During the aspiration care should be taken not to disturb the interface between the semen sample and the media.*
5. If further concentration of the aspirated sperm medium is needed, add 5 ml of ORIGIO® Sperm Wash, mix and centrifuge at 300-500 g for 5 minutes.
6. Aspirate the supernatant and re-suspend

the remaining pellet in a suitable volume of appropriate medium according to further procedure. Store the capped tubes at room temperature (20-25°C) until use.

Note: For IVF procedures it is advised to use a specialized fertilization medium (e.g. ORIGIO® Sequential Fert™) when re-suspending the pellet (step 6). 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 6).

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}

Gradient separation:

Please refer to the IFU supplied with the ORIGIO® Gradient™ 100, 90 and 40/80. (REF. no. 8400, 8401 and 8402).

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

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

