

OVOIL



Indication for use

Oil for covering of medium during in vitro fertilisation and micro-manipulation procedures.

Contraindications

None known.

Product Description

OVOIL™ is a sterile, light paraffin oil.

For use after equilibration at +37°C and 5 % CO₂, 6 % CO₂ or ambient atmosphere, depending on the intended use.

Storage instructions and stability

Store dark at +2 to +37°C.

OVOIL is stable until the expiry date shown on the container labels and the LOT-specific Certificate of Analysis.

Bottles can be used for up to two weeks after first opening, using aseptic technique. Opening of the bottle shall be limited to the time needed to remove the necessary amount of product. Record the opening date on the bottle. Discard excess product no later than two weeks after first opening.

Directions for use

The product shall be used by an IVF professional.

The patient target group is an adult or reproductive-age population that undergoes fertility treatment.

Remove OVOIL from vial using a sterile, non-toxic pipette. Do not pour.

Using a sterile, non-toxic pipette, add culture medium to a vessel labeled with patient ID. For large volume culture, add 0.5 to 1.0 mL to a sterile tube or well and cover entirely with OVOIL. For small volume culture, place 10 to 100 µL droplets in a sterile culture dish and cover entirely with OVOIL.

Rinse the catheter in case of aspiration of embryo(s) from medium under oil.

Specifications

Aseptically filtered

Mouse Embryo Assay, one-cell system [% embryos developed to expanded blastocyst at 96 hours] ≥ 80

Micro droplet Mouse Embryo Assay, one-cell system [% embryos developed to expanded blastocyst at 96 hours] PASS

Human Sperm Oil Assay PASS

Bacterial endotoxins (LAL assay) [EU/mL] < 0.25

LOT specific test results are available on the Certificate of Analysis provided with each delivery.

Warnings

Do not use after the expiration date.

Do not re-sterilize after opening.

Use within two weeks of opening.

Discard product if bottle integrity is compromised. Do not use OVOIL if it appears cloudy.

To avoid contamination Vitrolife strongly recommends that product should be opened and used only with aseptic technique.

Precautions

Caution: Federal (US) law restricts this device to sale by or on the order of a physician or practitioner trained in its use (Rx only).

The risk of reproductive and developmental toxicity for IVF products, including Vitrolife's IVF products has not been determined and is uncertain.

Not for injection.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.

Discard the product according to standard clinical practice for medical hazardous waste when the procedure is finished.

Symbols glossary

* Medical devices – Symbols to be used with information to be supplied by the manufacturer (ISO 15223-1:2021)

Symbol	Title	Reference and symbol ID
	Manufacturer	*Ref no: 5.1.1
	Date of manufacture	*Ref no: 5.1.3
	Use-by date	*Ref no: 5.1.4
	Batch code	*Ref no: 5.1.5
	Catalogue number	*Ref no: 5.1.6
	Sterilized using aseptic processing techniques	*Ref no: 5.2.2
	Single sterile barrier system	*Ref no: 5.2.11
	Keep away from sunlight (light sources)	*Ref no: 5.3.2
	Temperature limit	*Ref no: 5.3.7
	Consult instructions for use	*Ref no: 5.4.3
	Medical Device	*Ref no: 5.7.7

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