



Instructions for the Use of Paraffin Oil P.G.

(Catalogue Numbers: LGPO-100, LGPO-500, AMPO-100)

PRECAUTIONS AND WARNINGS

- Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- Caution:** The user should read and understand the Instructions for Use, Precautions and Warnings, and be trained in the correct procedure before using Paraffin Oil P.G.
- Not to be used for injection.
- Do not resterilize.
- Do not use the product if:
 - the product packaging appears damaged or if the seal is broken
 - the expiry date has been exceeded
 - the product becomes discolored, cloudy, or shows evidence of particulate matter
- To avoid problems with contamination, practice aseptic techniques.
- Once the bottle is opened, store the product tightly capped at 15-25°C and protected from light.

GENERAL INFORMATION

Indications for Use

An oil overlay for droplets of medium for embryo culture or manipulation.

Storage and Shelf Life

Store at 15-25°C and protected from light. Two (2) years from the date of manufacture.

Composition

A pharmaceutical grade light paraffin oil, pre-washed with water.

QUALITY CONTROL SPECIFICATIONS

Assay (performed for each batch)	Specification
Biological Tests	
Endotoxin (LAL)	≤ 0.5 EU/ml
Sterility Test (bacterial and fungal screen, SAL 10 ⁻³)	PASS
Biological Assays	
1-cell Mouse Embryo Assay (% expanded blastocysts at 96 h of culture)	≥ 80%

INSTRUCTIONS FOR USE

The procedures described below have been found to be effective for the preparation of Paraffin Oil P.G. for culture of human embryos and are offered only as examples. Every laboratory must define and optimize its own procedures.














Approximately 48 hours before preparing culture dishes for embryo culture:

- Place 50 ml of HTF (without HSA) into a 250 ml tissue culture flask and overlay with 200 ml of Paraffin Oil P.G.



- Gas the HTF slowly with 5:5:90 Blood Gas Mixture using a sterile serological pipette for 30 minutes. Allow the medium/oil to equilibrate for 24 hours at room temperature.
- After 24 hours, remove the HTF and replace with fresh HTF.
- Gas the HTF slowly with 5:5:90 Blood Gas Mixture using a sterile serological pipette for 15 minutes.
- Repeat the gassing process daily until the Paraffin Oil P.G. has been completely used.
- Alternatively, the flask containing medium and oil can be equilibrated in an incubator. If this procedure is used, allow 72 hours of incubation to ensure that the oil warms up and become saturated with gas. Be sure not to tighten the cap of the flask on the culture medium because this will prevent gas exchange.

SYMBOLS

	RX Only				
Sterile Using Aseptic Processing Techniques	By Prescription Only	Catalogue Number	Batch Code	Consult Instructions For Use	Manufacturer
					
Keep Away From Sunlight	Temperature Limitation	Authorized Representative in the European Community	Use By	GS1 DataMatrix Barcode	Do Not Resterilize
					
European Conformance (notified body)	Do Not Use if Package is Damaged				