



Instructions for the Use of global®

(Catalogue Numbers: LGGG-020, LGGG-050, LGGG-100, LGGG-250)

Let the Embryos Choose!®

'Uninterrupted Culture Medium'®

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 global® for human embryo culture or transfer.
- Not to be used for injection.
- Devices are not intended for resterilization.
- 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
- global® contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
- To avoid problems with contamination, practice aseptic techniques.
- Discard unused medium within 7 days of opening. Do not use after expiry date.

GENERAL INFORMATION

Indications for Use

Culture of human embryos from zygote to blastocyst, embryo transfer.

Storage and Shelf Life

Store at 2-8°C and protected from light. Ten (10) weeks from the date of manufacture.

Composition

A bicarbonate-buffered medium replete with glucose, lactate, pyruvate and all 20 amino acids is optimal to support the growth and development of human embryos in vitro.

Sodium Chloride	Sodium Pyruvate	L-Arginine	L-Threonine	Potassium Chloride
L-Alanine	L-Cystine	L-Tryptophan	Calcium Chloride	L-Asparagine
L-Histidine	L-Tyrosine	Potassium Phosphate	L-Aspartic Acid	L-Isoleucine
L-Valine	Magnesium Sulfate	L-Glutamic Acid	L-Leucine	Glycyl-L-Glutamine
Sodium Bicarbonate	Glycine	L-Lysine	EDTA	Glucose
L-Proline	L-Methionine	Phenol Red	Sodium Lactate	L-Serine
L-Phenylalanine	Gentamicin Sulfate* (10 µg/ml)			

*from therapeutic-grade source material



QUALITY CONTROL SPECIFICATIONS

Assay (performed for each batch)	Specification
Physicochemical Tests	
pH (with 5% CO ₂)	7.2-7.4
Osmolality	260-270 mOsM
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%

Special Note on the CO₂ Concentration in the Incubator: In most cases, a 5-7% concentration of CO₂ in the incubator will produce a pH of 7.2 to 7.4 in global[®]. However, the exact concentration of CO₂ required to produce the optimum pH of approximately 7.30 (7.27-7.33) depends on several factors, including the physical characteristics of incubator and the altitude. Consequently, we strongly recommend that each laboratory determine and use the concentration of CO₂ that is required to produce a pH of 7.30 in global[®].

INSTRUCTIONS FOR USE

The procedures described below have been found to be effective for the preparation of global[®] for culture of human embryos from zygote to blastocyst, and embryo transfer. Every laboratory must define and optimize its own procedures.

After each time the original bottle is opened recap the bottle tightly and store at 2-8°C, protected from light.

Twenty-four (24) hours prior to the use of global[®], supplement the medium with either Human Serum Albumin (HSA) or LifeGlobal[®] Protein Supplement to achieve desired % (v/v) of protein supplementation.

- Using a sterile pipette or tip, dispense 25-100 µl droplets or in larger volumes (0.5-1.0 ml) of global[®] supplemented with protein. Cover droplets with appropriate oil.
- Before introducing the embryos, place the culture dishes in the incubator for a minimum of 8 hours to ensure CO₂ and temperature equilibration. Label each dish with patient information.
- On Day 1, place the zygotes into the equilibrated global[®]. Culture the embryos for 48 h (Day 3, 4-8 cell stage).
- For further culture to the blastocyst stage:
 - transfer the cleavage-stage embryos to fresh medium under fresh oil and return to the incubator
 - maintain the embryos in the same medium (See Reed *et al.*, 2009; 2010). Note that such uninterrupted culture requires special attention to air quality.
- For transfer on Day 3 (cleavage stage) or Day 5/6 (blastocyst stage) follow general laboratory practice, and transfer to the uterus in 20-30 µl of equilibrated global[®] supplemented with protein.

References

- Reed ML, Hamic A, Thompson DJ and Caperton CL, *Fertil Steril* **92**, 1783-6, 2009
- Reed ML, Hamic A, Thompson DJ and Caperton CL, *J. Clin. Embryol.* **13**, 33-41, 2010)










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SYMBOLS

STERILE A	RX Only	REF	LOT		
Sterile Using Aseptic Processing Techniques	By Prescription Only	Catalogue Number	Batch Code	Consult Instructions For Use	Manufacturer
		EC REP			
Keep Away From Sunlight	Temperature Limitation	Authorized Representative in the European Community	Use By	European Conformance (notified body)	GS1 DataMatrix Barcode