



Instructions for the Use of global® for Fertilization

(Catalogue Numbers: LGGF-020, LGGF-050, LGGF-100, LGGF-500)

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 Fertilization for holding human cumulus-oocyte complexes prior to conventional in-vitro fertilization or ICSI, and for conventional in-vitro fertilization.
- 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® for Fertilization 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

For holding human cumulus-oocyte complexes prior to IVF or ICSI and for conventional IVF.

Storage and Shelf Life

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

Composition

For fertilization to occur, a single sperm must pass through the cumulus cells, interact with the zona pellucida, fuse with the oolemma and decondense inside the ooplasm. The fertilization medium must meet the metabolic requirements of the sperm, cumulus cells, and oocyte.

Sodium Chloride	Potassium Chloride	Calcium Chloride	Potassium Phosphate	Magnesium Sulfate
Sodium Bicarbonate	Glucose	Lactate Na Salt	Sodium Pyruvate	Glycine
L-Alanine	L-Arginine HCl	L-Asparagine	L-Aspartic Acid	L-Cystine
L-Glutamic Acid	Glycyl-Glutamine	L-Histidine	L-Isoleucine	L-Leucine
L-Lysine HCl	L-Methionine	L-Phenylalanine	L-Proline	L-Serine
L-Threonine	L-Tryptophan	L-Tyrosine	L-Valine	EDTA
Phenol Red	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® for Fertilization. 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® for Fertilization.

INSTRUCTIONS FOR USE

The procedures described below have been found to be effective for the preparation of global® for Fertilization for holding human cumulus-oocyte complexes prior to conventional fertilization or ICSI, and for conventional in-vitro fertilization. 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® for Fertilization, 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® for Fertilization supplemented with protein. Cover the oocyte-holding and fertilization microdrops dishes with appropriate oil and place the dishes in a CO₂ incubator overnight for gas and temperature equilibration.
- Before introducing the oocytes, place the dishes in the incubator for a minimum of 8 hours to ensure CO₂ and temperature equilibration. Label each dish with patient information.
- At the conclusion of the retrieval, dissect the oocytes to remove any degenerate and/or excess cumulus cells, blood and debris, and wash the oocytes. Place the oocyte-holding dishes into a CO₂ incubator and culture for 4-6 hours.
- Transfer oocytes into the supplemented global® for Fertilization microdrops in the oocyte-holding dishes.
- At time of conventional insemination, add sufficient sperm to each microdrop of supplemented global® for Fertilization in the fertilization dishes to produce the required sperm concentration.
- Let the fertilization dishes sit for several minutes and then examine each microdrop to ensure that the sperm concentration is appropriate.
- Transfer the oocytes from the oocyte-holding dishes to the sperm-containing microdrops in the fertilization dishes. Place the fertilization dishes into a CO₂ incubator and culture for 15-17 hours (overnight).



EC REP



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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		CE 0086	
Keep Away From Sunlight	Temperature Limitation	Authorized Representative in the European Community	Use By	European Conformance (notified body)	GS1 DataMatrix Barcode