



## Instructions for the Use of global® w/ HEPES

(Catalogue Numbers: LGGH-050, LGGH-100, LGGH-250, LGGH-500)

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### PRECAUTIONS AND WARNINGS

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- 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 the global® w/ HEPES for embryo washing and handling.
- 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® w/ HEPES contains only a low concentration of sodium bicarbonate and should not be gassed, or used for culture under CO<sub>2</sub>.
- global® w/ HEPES 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.

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### GENERAL INFORMATION

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#### Indications for Use

Embryo washing and handling.

#### Storage and Shelf Life

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

#### Composition

A HEPES-buffered medium is required when embryos are handled outside of a CO<sub>2</sub> incubator.

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	HEPES	Gentamicin Sulfate* (10 µg/ml)		

\*from therapeutic-grade source material


**QUALITY CONTROL SPECIFICATIONS**












Assay (performed for each batch)	Specification
<b>Physicochemical Tests</b>	
pH	7.2-7.4
Osmolality	260-270 mOsM
<b>Biological Tests</b>	
Endotoxin (LAL)	≤ 0.5 EU/ml
Sterility Test (bacterial and fungal screen, SAL 10 <sup>-3</sup> )	PASS
<b>Biological Assays</b>	
1-cell Mouse Embryo Assay (% expanded blastocysts at 96 h of culture after 1 h exposure)	≥ 80%

**INSTRUCTIONS FOR USE**

The procedures described below have been found to be effective for the preparation of global® w/ HEPES for embryo washing and handling. Every laboratory must define and optimize its own procedures.

1. Open the bottle and add a sufficient volume of Human Serum Albumin (HSA) or LifeGlobal® Protein Supplement to produce a desired final concentration of HSA or LifeGlobal® Protein Supplement in the medium. Cap and gently agitate the bottle to completely mix the HSA or LifeGlobal® Protein Supplement into the medium.
2. Aliquot the volume of supplemented global® w/ HEPES needed for one patient or one day into appropriate embryo-safe culture tubes. Cap the tubes tightly and store at 2-8°C, protected from light.
3. To wash oil, place 50 ml of global w/ HEPES (without HSA or LifeGlobal® Protein) into a tissue culture flask and overlay with 250 ml of oil. Agitate flask. Store at 2-8°C.
4. The night before intended use aliquot a sufficient volume of washed oil into embryo-safe culture tubes. Cap the tubes and place them into a heating block at 37°C, overnight.
5. The night before or the morning of intended use, place a sufficient number of tubes of supplemented global® w/ HEPES into a heating block at 37°C.
6. Prepare a sufficient number of plates containing micro-drops of supplemented global® w/ HEPES under washed oil.
7. Cover and seal the dishes and place into the incubator for final temperature equilibration for 1-2 hours.

**SYMBOLS**

	<b>RX Only</b>				
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	European Conformance (notified body)	GS1 DataMatrix Barcode