



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

(Catalogue Numbers: LGGH-050, LGGH-100, LGGH-250, LGGH-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 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.

### GENERAL INFORMATION

#### 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>STERILE A</b>	<b>RX Only</b>	<b>REF</b>	<b>LOT</b>		
Sterile Using Aseptic Processing Techniques	By Prescription Only	Catalogue Number	Batch Code	Consult Instructions For Use	Manufacturer
		<b>EC REP</b>		<b>CE</b> 0086	
Keep Away From Sunlight	Temperature Limitation	Authorized Representative in the European Community	Use By	European Conformance (notified body)	GS1 DataMatrix Barcode