



Instructions for the Use of global[®] total[®] w/ HEPES

(Catalogue Numbers: LGTH-050, LGTH-100, LGTH-250)

PRECAUTIONS AND WARNINGS

1. **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
2. **Caution:** The user should read and understand the Instructions for Use, Precautions and Warnings, and be trained in the correct procedure before using global[®] total[®] w/ HEPES for human oocyte and embryo washing and manipulation, ICSI or embryo transfer.
3. Not to be used for injection.
4. Do not resterilize.
5. 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
6. This product contains human serum albumin, a derivative of human blood. The human serum albumin used in the preparation of this product has been heated at 60°C for ten hours.

Caution: Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes. It is strongly recommended that every time that global[®] total[®] w/ HEPES is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

7. global[®] total[®] w/ HEPES contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
8. To avoid problems with contamination, practice aseptic techniques.
9. Discard unused medium within 7 days of opening. Do not use after expiry date.

GENERAL INFORMATION

Indications for Use

Human oocyte and embryo washing and manipulation, fertilization by intracytoplasmic sperm injection (ICSI), embryo transfer.

Storage and Shelf Life

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

Disposal Consideration

Treat or dispose of waste material in accordance with all local state/provincial, and national requirements. Dispose with laboratory waste.

Composition

A HEPES-buffered medium is required when oocytes and embryos are handled outside of a CO₂ incubator.



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	HEPES	Human Serum Albumin* (4.4 mg/ml)		
Human α - and β -globulins* (0.6 mg/ml)		Gentamicin Sulfate* (10 μ g/ml)		

*from therapeutic-grade source material

QUALITY CONTROL SPECIFICATIONS












Assay (performed for each batch)	Specification
Physicochemical Tests	
pH	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)	$\geq 80\%$

INSTRUCTIONS FOR USE

The procedures described below have been found to be effective for human oocyte and embryo washing and manipulation, ICSI or embryo transfer. Every laboratory must define and optimize its own procedures.

- For oocyte and embryo washing and manipulation, prepare culture dishes containing 25-100 μ l droplets under oil, or in larger volumes (0.5-1.0 ml) of global[®] total[®] w/ HEPES, according to general laboratory practice.
- Before introducing the oocytes or embryos, warm the culture dishes for sufficient time to ensure temperature equilibration.
- For washing, pass the oocytes or embryos through several droplets of global[®] total[®] w/ HEPES, according to general laboratory practice.
- Before ICSI or other manipulation, wash the oocytes or embryos, according to general laboratory practice.
- For ICSI, prepare 5-10 small droplets (5-10 μ l) of global[®] total[®] w/ HEPES in the ICSI dish, next to the PVP droplets and cover them with oil, according to general laboratory practice. Transfer the oocytes to the respective droplets just before the ICSI procedure.
- For transfer, wash the embryos according to general laboratory practice, and transfer to the uterus in 20-30 μ l of global[®] total[®] w/ HEPES.
- Immediately prior to transfer, rinse the transfer catheter with global[®] total[®] w/ HEPES.

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