



Instructions for the Use of global[®] total[®] LP

(Catalogue Numbers: H5GT-010, H5GT-030, H5GT-060, H5GT-100)

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[®] total[®] LP for the culture of human embryos from zygote to blastocyst, embryo transfer.
- Not to be used for injection.
- Do not resterilize.
- 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
- 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[®] LP 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.

- global[®] total[®] LP 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.

Disposal Consideration

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

Composition

| | | | | |
|--------------------|--------------------|------------------|---------------------|-------------------|
| 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 | Human Serum Albumin* (5 mg/ml) | 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[®] total[®] LP. 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[®] total[®] LP.

INSTRUCTIONS FOR USE

The procedures described below have been found to be effective for the culture of human embryos from zygote to blastocyst, embryo transfer and are offered only as examples. Every laboratory must define and optimize its own procedures.

1. Prepare culture dishes containing 25-100 µl droplets or in larger volumes (0.5-1.0 ml) of global[®] total[®] LP under oil, according to general laboratory practice.
2. Before introducing the embryos, place the culture dishes in the incubator for sufficient time to ensure CO₂ and temperature equilibration. Depending on the exact configuration, this may take from 24-48 hours. Equilibration will require less time if the oil and medium have been pre-equilibrated.
3. On Day 1, place the zygotes into the equilibrated global[®] total[®] LP. Culture the embryos for 48 h (Day 3, 4-8 cell stage).
4. For further culture to the blastocyst stage:
 either a) transfer the cleavage-stage embryos to fresh medium under fresh oil and return to the incubator
 or b) maintain the embryos in the same medium (See Reed *et al.*, 2009; 2010). Note that such uninterrupted culture requires special attention to air quality.
5. 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[®] total[®] LP.
6. Immediately prior to transfer, rinse the transfer catheter with global[®] total[®] LP.

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)



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 | | | |
| Keep Away From Sunlight | Temperature Limitation | Authorized Representative in the European Community | Use By | GS1 DataMatrix Barcode | Do Not Resterilize |
| CE 0086 | | | | | |
| European Conformance (notified body) | | | | | |