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## Instructions for the Use of global<sup>®</sup> total<sup>®</sup> LP for Fertilization

(Catalogue Numbers: H5TF-010, H5TF-020, H5TF-050, H5TF-100)

### 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<sup>®</sup> total<sup>®</sup> LP for Fertilization for the culture and conventional in-vitro fertilization of human oocytes.
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<sup>®</sup> total<sup>®</sup> LP for Fertilization 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<sup>®</sup> total<sup>®</sup> LP for Fertilization 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 culture and fertilization.

#### 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* (10µg/ml)		

\*from therapeutic-grade source material

## QUALITY CONTROL SPECIFICATIONS

Assay (performed for each batch)	Specification
<b>Physicochemical Tests</b>	
pH (with 5% CO <sub>2</sub> )	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)	≥ 80%

**Special Note on the CO<sub>2</sub> Concentration in the Incubator:** In most cases, a 5-7% concentration of CO<sub>2</sub> in the incubator will produce a pH of 7.2 to 7.4 in global<sup>®</sup> total<sup>®</sup> LP for Fertilization. However, the exact concentration of CO<sub>2</sub> 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 CO<sub>2</sub> that is required to produce a pH of 7.30 in global<sup>®</sup> total<sup>®</sup> LP for Fertilization.

## INSTRUCTIONS FOR USE

The procedures described below have been found to be effective for human oocyte culture and fertilization and are offered only as examples. Every laboratory must define and optimize its own procedures.

1. Prepare dishes for oocyte holding and/or fertilization, containing small droplets (25-100 µl) or larger volume (0.5-1.0 ml) of global<sup>®</sup> total<sup>®</sup> LP for Fertilization under oil, according to general laboratory practice.
2. Place the culture dishes in the incubator for sufficient time to ensure CO<sub>2</sub> 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. 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, according to your standard laboratory procedures.
4. Transfer the oocytes into the global<sup>®</sup> total<sup>®</sup> LP for Fertilization droplets in the oocyte-holding dishes (1-2 oocytes/ droplet).
5. Place the oocyte-holding dishes into a CO<sub>2</sub> incubator and culture for 3-6 hours.
6. Add sufficient sperm to each droplet of global<sup>®</sup> total<sup>®</sup> LP for Fertilization in the fertilization dishes to produce the required sperm concentration.
7. Let the fertilization dishes sit for several minutes and then examine each droplet to ensure that the sperm concentration is appropriate.
8. Transfer the oocytes from the oocyte-holding dishes to the sperm-containing droplets in the fertilization dishes (1-2 oocytes/microdrop).
9. Place the fertilization dishes into a CO<sub>2</sub> incubator and culture.
10. The next day, evaluate the oocytes for evidence of fertilization, and wash and transfer them to embryo culture medium, according to your standard laboratory procedures.



EC REP

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