






Instructions for the Use of global[®] Collect[™]

Special Note:  global[®] Collect[™] must be used at 37°C.

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 Directions for Use, Precautions and Warnings, and be trained in the correct procedure before using  global[®] Collect[™] for oocyte retrieval and washing.

I. Precautions and Warnings

1. Not to be used for injection
2.  global[®] Collect[™] contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic
3.  global[®] Collect[™] must be used at 37°C. The pH of  global[®] Collect[™] is balanced for use at 37°C.
4.  global[®] Collect[™] contains only a low concentration of sodium bicarbonate and should not be gassed, or used for culture under CO₂.
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. Record on the label: Date Received and Date Opened
7. To avoid problems with contamination, practice aseptic techniques and discard minimal amounts of excess medium remaining in the bottle.
8. Once the bottle is opened, store the product tightly capped at 2-8°C and protected from light.
9. Discard unused medium within 7 days of opening.

II. General Information

Indications for Use: For oocyte retrieval and washing.

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

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
Gentamicin	Phenol Red	HEPES

Storage: Store at 2-8°C and protected from light.

Shelf Life: No more than 8 weeks from the date of release. For best results, use within four weeks.

Quality Control Specifications

	<u>Specification</u>
Physiochemical tests:	
• pH at room temperature	7.35-7.45
• pH at 37°C	7.20-7.30
• Osmolality	260-270
Biological Tests	
• LAL Endotoxin	<0.5 EU/ml
• Sterility Test, membrane filtration	Negative
1-cell Mouse Embryo Assay (% blastocysts at 96h of culture)	>80%

III. Disclaimer

The procedures described below have been found to be effective for the retrieval and washing of human oocytes and are offered only as examples. Every laboratory must define and optimize its own procedures.

IV. Directions for Use

1. **LifeGlobal® Collect™** should be supplemented with **LifeHSA** or **LifeProtein Supplement**, according to standard laboratory protocols, prior to use.
2. Warm the protein-supplemented **LifeGlobal® Collect™** to 37°C

For each patient:

3. Prepare sufficient oocyte culture dishes containing drops of protein-supplemented **LifeGlobal for Fertilization** under oil, and place in the incubator for CO₂ and temperature equilibration. These will be used for culture of the oocytes prior to conventional fertilization or ICSI.
4. Just prior to oocyte retrieval, prepare oocyte washing dishes by decanting warmed protein-supplemented **LifeGlobal® Collect™** into an appropriate number of culture dishes, and cover with warmed **LifeLiteOil**, **LifeParaffin Oil**, or **LifeGuard Oil**, according to standard laboratory protocols.
5. Place the oocyte washing dishes on a warmed surface in the laminar flow hood to maintain at 37°C.
6. Gently swirl each oocyte collection tube and decant the contents into a warmed searching dish.
7. Search for the oocytes under a dissecting microscope.
8. Using a sterile pipette, transfer each oocyte into the initial wash dish containing warmed protein-supplemented **LifeGlobal® Collect™**.
9. Wash each oocyte, and remove the degenerated and excess cumulus cells, debris and blood, according to standard laboratory protocols. Transfer all oocytes to a second oocyte washing dish of warmed protein-supplemented **LifeGlobal® Collect™**.
10. Pass the washed oocytes through drops of **LifeGlobal for Fertilization**, according to standard laboratory protocols, and place in the incubator until conventional fertilization or ICSI.