



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

(Catalogue Numbers: GCOL-100, GCOL-500)

Special Note: global[®] Collect[®] must be used at 37°C: The pH of global[®] Collect[®] is balanced for use at 37°C.

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[®] Collect[®] for oocyte retrieval and washing.
3. Not to be used for injection.
4. Devices are not intended for resterilization.
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. global[®] Collect[®] contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
7. global[®] Collect[®] contains only a low concentration of sodium bicarbonate and should not be gassed, or used for culture under CO₂.
8. To avoid problems with contamination, practice aseptic techniques and discard minimal amounts of excess medium remaining in the bottle.
9. Once the bottle is opened, store the product tightly capped at 2-8°C and protected from light.
10. Discard unused medium within 7 days of opening. Do not use after expiry date.

GENERAL INFORMATION

Indications for Use

Oocyte retrieval and washing.

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 oocytes are handled outside of a CO₂ 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
Physicochemical Tests	
pH (at room temperature)	7.4-7.45
pH (at 37°C)	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%

INSTRUCTIONS FOR USE












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.

- global® Collect® should be supplemented with Human Serum Albumin (HSA) or LifeGlobal® Protein Supplement to achieve desired % (v/v) of protein supplementation.
- Warm the protein-supplemented global® Collect® to 37°C prior to use.

For each patient:

- On the day prior to oocyte retrieval, prepare sufficient oocyte culture dishes containing drops of protein-supplemented global® for Fertilization under appropriate oil, and place in the incubator for CO₂ and temperature equilibration. These will be used for culture of the oocytes.
- Just prior to oocyte retrieval, prepare oocyte washing dishes by decanting warmed protein-supplemented global® Collect® into an appropriate number of culture dishes, and cover with warmed oil.
- Place the oocyte washing dishes on a warmed surface in the laminar flow hood to maintain at 37°C.
- Using a sterile pipette, transfer each oocyte into the initial wash dish containing warmed protein-supplemented global® Collect®. Wash each oocyte, and remove the degenerated and excess cumulus cells, debris and blood.
- Transfer all oocytes to a second oocyte washing dish of warmed protein-supplemented global® Collect®. Hold oocytes in this dish until end of oocyte retrieval but not longer than 20 -30 minutes. Place the cleaned oocytes through drops of global® for Fertilization. Rinse thoroughly.
- Move oocytes in new drops of global® for Fertilization and place in the incubator until conventional fertilization or ICSI.

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	European Conformance (notified body)	GS1 DataMatrix Barcode