



CE Instructions for the Use of global® DMSO Blastocyst Vitrification Warming Kit

0086

(Catalogue Numbers: DMW5-005)

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® DMSO Blastocyst Vitrification Warming Kit for rehydration of human blastocysts.
3. **Warning:** The long term safety of blastocyst rehydration on children born from this procedure is unknown.
4. **Warning:** The safety and effectiveness of vitrification has not been fully evaluated in human embryos that have not yet reached the blastocyst stage of development.
5. Not to be used for injection.
6. Do not resterilize.
7. 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
8. 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® DMSO Blastocyst Vitrification Warming Kit 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.
9. global® DMSO Blastocyst Vitrification Warming Kit contains the antibiotic gentamicin sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
10. To avoid problems with contamination, practice aseptic techniques.
11. Use a legally marketed carrier and storage device appropriate for blastocyst rehydration procedures.
12. Use a closed storage system to prevent the potential risk of viral contamination and do not use open storage systems where the sample comes in direct contact with liquid nitrogen.
13. The global® DMSO Blastocyst Vitrification Warming Kit is intended **for single use only** (the rehydration of blastocysts from one patient on one day). For use with human blastocysts that have been vitrified using the global® DMSO Blastocyst Vitrification Kit. Discard any unused product after opening.

GENERAL INFORMATION

Indications for Use

For recovery and rehydration of human blastocysts.

Storage and Shelf Life

Store at 2-8°C and protected from light. One (1) year 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 – base components

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)		

Warming Solution 1

Sucrose (1.0 M)
Human Serum Albumin* (10 mg/ml)

Warm Solution 2

Sucrose (0.5 M)
Human Serum Albumin* (10 mg/ml)

Warming Solution 3

Human Serum Albumin* (10 mg/ml)

*from therapeutic-grade source material

QUALITY CONTROL SPECIFICATIONS

The solutions in the global® DMSO Blastocyst Vitrification Warming Kit are membrane filtered and aseptically processed according to cGMP procedures which have been validated to meet a sterility assurance level (SAL) of 10^{-3} .

Assay (performed for each batch)	Specification
MEDIA	
Physicochemical Tests	
pH – Warming Solution 1, Warming Solution 2, Warming Solution 3	7.1-7.5
Osmolality – Warming Solution 1	1180-1320 mOsM
Osmolality – Warming Solution 2	800-875 mOsM
Osmolality – Warming Solution 3	270-300 mOsM
Biological Tests	
Endotoxin (LAL) – Warming Solution 1, Warming Solution 2, Warming Solution 3	≤ 1.0 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 following step-in, step-out of vitrification and warming solutions)	≥ 80%
EMBRYO GPS® DISHES	
Physicochemical Tests	
Endotoxin (LAL)	< 20 EU/device
Biological Tests	
1-cell Mouse Embryo Assay (% expanded blastocysts after 96 h)	≥ 80%














INSTRUCTIONS FOR USE

1. The rehydration procedures are to be performed at 20-27°C.



2. Bring the global[®] DMSO Blastocyst Vitrification Warming Solutions (Warming Solution 1, Warming Solution 2 and Warming Solution 3) to room temperature before use. Mix gently the content of each vial.
3. Refer to the manufacturer's instruction for use of the carrier device that has been used for specific instructions pertaining to that device.
4. Fill the Liquid Nitrogen reservoir with Liquid Nitrogen to a sufficient depth to completely submerge a goblet containing the carrier device containing the vitrified samples to be warmed. Quickly transfer the cryocane from the storage tank to the reservoir, keeping the carrier device under Liquid Nitrogen at all times.
5. Aseptically dispense a 20 µl drop of Warming Solution 1 into a Petri dish 1 (W1a).
6. Dispense two 20 µl drops of Warming Solution 2 into same dish (W2a & W2b).
7. Thaw only one carrier device at a time. Carefully remove the carrier device from the cane, keeping the part containing the blastocyst(s) under the surface of the Liquid Nitrogen.
8. Follow the directions for use that accompany the carrier device used to warm and open the vitrification device, and then immediately dispense the contents of the device (approximately 1 µl) onto the Petri dish.
9. Draw up approximately 1 µl of solution from W1a, and dispense it adjacent to the drop containing the blastocyst(s). Use the vitrification device to merge the two drops, and then allow gradual mixing for 1 minute.
10. Draw up a small amount of W1a into the transfer pipette and move blastocyst(s) in W1a.
11. Hold the blastocyst(s) in W1a for 1 minute.
Note: After each transfer of blastocyst(s) described in the following steps, eject any remaining fluid in the transfer pipette and draw up some solution from the next drop, prior to the next manipulation.
12. Transfer the blastocyst(s) from W1a to W2a and hold for 2 minutes.
13. Transfer the blastocyst(s) from W2a to W2b for 2 minutes.
14. During the holding time in W2b, dispense three (3) 20 µl drops of Warm 3 into the Petri dish (W3a, W3b & W3c).
15. Transfer the blastocyst(s) from W2b to W3a and hold for 3 minutes.
16. Transfer the blastocyst(s) from W3a to W3band hold for 3 minutes.
17. Transfer the blastocyst(s) from W3b to W3c and hold for 3 minutes.
18. Finally, transfer the blastocyst(s) to a dish of pre-equilibrated appropriate culture medium and incubate in a CO₂ incubator at 37°C for 3-4 hours to allow for further recovery prior to further manipulations and/or transfer.

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	Do Not Reuse	GS1 DataMatrix Barcode
					
Do Not Resterilize	European Conformance (notified body)				