

Fast Freeze® Thaw Kit





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Product Description:	For the rehydration of human blastocysts.
Catalogue Number(s)	Unit Size
GFT5-055	1 kit (5 ml)
Intended Use	Why choose?
Composition	Storage Instructions
Shelf Life	Recommendations
Quality Control Specifications	

Intended Use	<p>global® Blastocyst Fast Freeze® Thawing Kit is designed for the rehydration of human blastocysts that have been cryopreserved using global® Blastocyst Fast Freeze® Kit.</p>																																												
Why would you choose global® Fast Freeze® Thaw Kit?	<p>global Blastocyst Fast Freeze® Thawing Kit is a five-step gradual rehydration process through reducing concentrations of sucrose in a global® w/HEPES base medium. The principals of the protocol have led to the birth of over 300 babies.</p>																																												
Composition	<table border="1"> <tr> <td colspan="4">2 X 5 ml vials of Thaw Solution 1 (white cap)</td> </tr> <tr> <td colspan="4">1 X 5 ml vial of Thaw Solution 2 (blue cap)</td> </tr> <tr> <td colspan="4">1 X 5 ml vial of Thaw Solution 3 (green cap)</td> </tr> <tr> <td colspan="4">1 X 5 ml vial of Thaw Solution 4 (yellow cap)</td> </tr> <tr> <td colspan="4">1 X 5 ml vial of Thaw Solution 5 (red cap)</td> </tr> <tr> <td colspan="4">10 X Universal GPS® dishes</td> </tr> <tr> <td colspan="4">Base Components</td> </tr> <tr> <td>Sodium Chloride</td> <td>Potassium Chloride</td> <td>Calcium Chloride</td> <td>Potassium Phosphate</td> </tr> <tr> <td>Magnesium Sulfate</td> <td>Sodium Bicarbonate</td> <td>Glucose</td> <td>Lactate Na Salt</td> </tr> <tr> <td>Sodium Pyruvate</td> <td>Amino Acids</td> <td>EDTA</td> <td>Gentamicin</td> </tr> <tr> <td>Phenol Red</td> <td>HEPES</td> <td></td> <td></td> </tr> </table> <p>Thaw 1, Thaw 2, Thaw 3, Thaw 4, and Thaw 5 contain decreasing concentrations of sucrose together with 10 mg/ml Human Serum Albumin (HSA) and the base components.</p>	2 X 5 ml vials of Thaw Solution 1 (white cap)				1 X 5 ml vial of Thaw Solution 2 (blue cap)				1 X 5 ml vial of Thaw Solution 3 (green cap)				1 X 5 ml vial of Thaw Solution 4 (yellow cap)				1 X 5 ml vial of Thaw Solution 5 (red cap)				10 X Universal GPS® dishes				Base Components				Sodium Chloride	Potassium Chloride	Calcium Chloride	Potassium Phosphate	Magnesium Sulfate	Sodium Bicarbonate	Glucose	Lactate Na Salt	Sodium Pyruvate	Amino Acids	EDTA	Gentamicin	Phenol Red	HEPES		
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Storage Instructions	Store at 2-8°C and protected from light.
Shelf Life	1 year from the date of manufacture.
Recommendations for Use	For a full and detailed recommended protocol of use for  lifeglobal® Blastocyst Fast Freeze® Thawing Kit please contact us at customerservice@lifeglobal.com .

Quality Control Specifications	Quality Control
	The solutions in the  lifeglobal® Blastocyst Fast Freeze® Thawing 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


	Specification
Physiochemical tests: (Base solution)	
• pH (Thaw 1, Thaw 2 & Thaw 3)	7.1-7.5
• Osmolality - Thaw 1	1100-1325
• Osmolality - Thaw 2	650-755
• Osmolality - Thaw 3	400-525
• Osmolality - Thaw 4	365-405
• Osmolality - Thaw 5	270-300
Biological Tests (Each kit solution)	
• LAL Endotoxin (Thaw 1, Thaw 2, Thaw 3, Thaw 4 & Thaw 5)	< 1.0 EU/ml
• Sterility Test, membrane filtration	Negative
Mouse Blastocyst Re-expansion Assay: (% re-expanded blastocysts at 24h of culture after step-in, step-out of all of the cryopreservation and thawing solutions)	≥ 80%
For Universal GPS® Dishes	
• LAL Endotoxin	< 0.5 EU/ml
• 1-cell Mouse Embryo Assay (% expanded blastocysts after 96 h)	≥ 80%

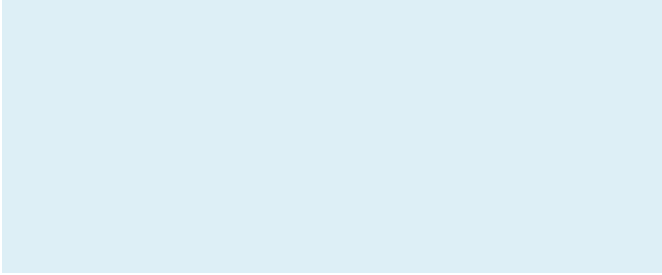

Precautions and Warnings

1. Not to be used for injection.
2. **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
3. 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: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBc, HCV, and HTLV I/II and non-reactive for HbsAg, HCV RNA and HIV-1 RNA and syphilis. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

4. **Warning:** The long term safety of blastocyst Fast Freeze® on children born from this procedure is unknown.
5. **Caution:** The safety and effectiveness of cryopreservation has not been fully evaluated in human embryos that have not yet reached the blastocyst stage of development.
6. **Caution:** The user should read and understand the Directions for Use, Precautions and Warnings, and be trained in the correct procedure before using the  **global® Blastocyst Fast Freeze® Thawing Kit** for the rehydration of human blastocysts.
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.

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8. The  **global® Blastocyst Fast Freeze® Thawing Kit** is intended for single use only (the rehydration of cryopreserved blastocysts from one patient on one day). Discard any unused product after opening.

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