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EN Instructions for the Use of global® Blastocyst Fast Freeze® Kit

(Catalogue Numbers: GFV5-005)

PRECAUTIONS AND WARNINGS

- Caufile 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 instructions for Use, Precautions and Warnings, and be trained in the correct procedure before using global® Blastocyst Fast Freeze® Kit for cryopreservation of human blastocysts.
- Warning: The long term safety of blastocyst cryopreservation on children born from this procedure is unknown.
- Warning: This kit is not intended to be used for the cryopreservation of human oocytes, or for human embryos that have not yet reached the blastocyst stage of development.
- Not to be used for injection.
- Do not sterilize.
- Do not reuse 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
- 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 medical 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, it is known that some products may contain infectious agents that cannot be totally excluded. This also applies to unknown or emerging viruses or agents that are not yet recognized. The manufacturer of this product is not responsible for reports of virus transmission to patients manufactured to European Pharmacopeia. Any adverse reactions to this product should be reported to the manufacturer. The global® Blastocyst Fast Freeze® Kit is then correctly recommended to consider the name and the number of the lot of product in power to avoid moment faire le lien entre le patient et le lot du produit.
- global® Blastocyst Fast Freeze® Kit contient du sulfate de gentamicine, un antibiotique. Il convient de prendre les mesures de précaution nécessaires pour s'assurer que la partie de l'antibiotique n'est pas dans le lot.
- Utiliser des techniques aseptiques pour éviter tout problème de contamination.
- Utiliser des paillettes de congélation adaptées pour les procédures de cryoconservation de blastocystes et suivre les instructions du fabricant pour l'étiquetage, la manipulation et le scelllement thermique des paillettes.
- Le global® Blastocyst Fast Freeze® Kit est destiné à un usage unique (la cryoconservation de blastocystes d'une patiente un jour donné). Jeter le produit non utilisé après ouverture.

INFORMATIONS GÉNÉRALES

- Indications d'utilisation Pour la cryoconservation de blastocystes.
- Conditions et durée de conservation À conserver entre 2 et 8 °C à l'abri de la lumière. Un (1) an à partir de la date de fabrication.
- Composition – composants de base Chlorure de sodium, Chlorure de calcium, Chlorure de potassium, Sulfate de magnésium, Bicarbonate de sodium, Glucose, Lactate de potassium, Pyruvate de sodium, Glycine, L-alanine, L-arginine HCl, L-asparagine, Acide L-aspartique, L-cystine, Acide L-glutamique, Glycyl-Glutamine, L-histidine, L-isoleucine, L-leucine, L-méthionine, L-proline, L-serine, L-threonine, L-tryptophane, L-tyrosine, L-valine, EDTA, Phenolol, HEPES, Albumine de sucre humaine* (20 mg/ml), Gentamicin Sulfate** (10 µg/ml).
- GENERAL INFORMATION Indications for Use For cryopreservation of 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.
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- For cryopreservation of blastocysts.
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*From therapeutic-grade source material
global® Blastocyst Fast Freeze® Solutions 1, 2, and 3 contain increasing concentrations of glycerol and ethylene glycol together with the base components.

QUALITY CONTROL SPECIFICATIONS

Assay (performed for each batch)	Specification
Physicochemical Tests	
pH – Fast Freeze® Solution 1, 2, 3	7.1-7.5
Osmolality – Fast Freeze® Solution 1	1400-2000 mOsm
Osmolality – Fast Freeze® Solution 2	4900-6900 mOsm
Osmolality – Fast Freeze® Solution 3	7800-10600 mOsm
Biological Tests	
Endotoxin (LAL) – Fast Freeze® Solution 1, 2, 3	< 1 EU/ml
Sterility Test (bacterial and fungal screen, SAL 10 ⁴)	PASS
Biological Assays	
Mouse Embryo Assay (% re-expanded blastocysts at 24 h of culture)	≥ 80%
UNIVERSAL GPS® DISHES	
Endotoxin (LAL)	< 20 EU/device
1-cell Mouse Embryo Assay (% blastocysts at 96 h of culture)	≥ 80%

INSTRUCTIONS FOR USE

- Note: Only full or expanded blastocysts of good quality with a visible/bien organized cavity and a distinct ICM or at the hatching/hatched stage should be chosen for cryopreservation.
- The best procedure to use is to bring the vials of global® Blastocyst Fast Freeze® Solutions 1, 2 and 3 (F1, F2 and F3) to room temperature before use. Mix gently each vial before use.
 - Label a goblet or cryoblock with the information of the patient.
 - Fill a liquid nitrogen reservoir with liquid nitrogen and keep container close to working area. Always maintain sufficient liquid nitrogen in the reservoir.
 - Prepare a label for each straw according to standard laboratory protocols. It is advisable to load only one blastocyst per straw.
 - Transfer the straw to the end of the straw on the cotton plug. Use a syringe to pull the cotton plug down past the label until approximately half of the cotton plug is visible in the straw.
 - For each blastocyst, label 3 of the smaller outer wells of the Universal GPS® dish as F1, F2 and F3. The label the two larger inner wells as F3R (to be used to rinse the freezing straw) and two of the smaller outer wells as F3L (to be used to load the freezing straw).
 - Transfer the straw to the appropriate well of the dish. Use the transfer pipette to gently move the blastocyst across the straw, away from the unreadable point, in order to dilute any carrier of culture medium.
 - Hold the blastocyst in F1 for 5 minutes.
 - Load pipette with 100 µl of fluid from the F2 to the F2 plug. Hold the blastocyst from the drop F1 to F2 for 5 minutes.
 - Transfer the blastocyst with the two larger inner wells F3 and the two smaller outer wells F3L from the dish to the labeled Universal GPS® dish. Use the transfer pipette to gently move the blastocyst across the straw, away from the unreadable point, in order to dilute any carrier of culture medium.
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 - Load pipette with 100 µl of fluid from the F3 to the F3 plug. Hold the blastocyst from the drop F2 to F3 for 5 minutes.
 - Transfer the blastocyst with the two larger inner wells F3 and the two smaller outer wells F3L from the dish to the labeled Universal GPS® dish. Use the transfer pipette to gently move the blastocyst across the straw, away from the unreadable point, in order to dilute any carrier of culture medium.
 - Load pipette with 100 µl of fluid from the F3 to the F3 plug. Hold the blastocyst from the drop F3 to F3R for 5 minutes.
 - Transfer the blastocyst with the two larger inner wells F3 and the two smaller outer wells F3L from the dish to the labeled Universal GPS® dish. Use the transfer pipette to gently move the blastocyst across the straw, away from the unreadable point, in order to dilute any carrier of culture medium.
 - Load pipette with 100 µl of fluid from the F3R to the F3R plug. Hold the blastocyst from the drop F3 to F3R for 5 minutes.
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