



0242-01

MediCult

Vitrification Warming

Product No.

1219

Symbols:

Catalogue Number



Batch Code



Sterilized using aseptic processing techniques (filtration)



Keep away from sunlight



Temperature limitation
from 2°C to 8°C



Use by



Consult operating instructions



Do not re-use



Technical Services:

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MediCult
Innovation with Care

Vitrification Warming

Intended use

For thawing human embryos vitrified by using MediCult Vitrification Cooling

Composition

Vial 1+2+3

Plasma protein fraction (Human) 5%, USP

Sucrose

Sodium lactate

Physiological salts

L-glutamine

Sodium bicarbonate

Penicillin 50.000 IU/l

Streptomycin 50 mg/l

Vial 4

Plasma protein fraction (Human) 5%, USP

Sodium lactate

Physiological salts

L-glutamine

Penicillin 50.000 IU/l

Streptomycin 50 mg/l

Quality control testing

Sterility tested (Ph.Eur., USP)

pH tested (Ph.Eur., USP)

Endotoxin tested ≤ 0.5 EU/ml (Ph.Eur., USP)

2 cell Mouse Embryo Assay (MEA) $\geq 80\%$ Blastocysts by 96h

Note: The results of each batch are stated on a Certificate of Analysis, which is available upon request.

Storage instructions and stability

Store in original container at 2-8°C, protected from light.

Do not freeze prior to use.

Whenever the product has been warmed, it should not be refrigerated again.

The product is packaged in vials intended for single use.

When stored as directed by the manufacturer the product is stable until the expiration date shown on the vial label.

Precautions and warnings

Do not use the product if:

1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

Do not re-use.

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

Caution: US federal law restricts this device to sale by or on the order of a physician (Rx only).

Instructions for use

1. Pre-warm the Warming Medium to 37°C for at least 30 minutes and keep other media at room temperature.
2. Collect the McGill Cryoleaf™ from the storage container and place into bath of LN₂.
3. Using forceps, remove the outer cover from the McGill Cryoleaf™. Take care that all parts of the McGill Cryoleaf™ remain immersed in LN₂ at all times.
4. Unlock the inner part with the tip and slide it upwards. Ensure that the McGill Cryoleaf™ still remains immersed in LN₂.
5. Take the McGill Cryoleaf™ out of the LN₂ and quickly transfer embryos into Warming Medium (2ml at 37°C). The embryos will then loosen from the McGill Cryoleaf™ and be released into Warming Medium, where they should stay for a maximum of 3 minutes (at this point, the embryos are still shrunken).
6. Using a suitable pipette, transfer the embryos into 2ml Dilution medium 1 (DM-1) for 3 minutes (at this point, the embryos partly recover their shape).
7. Transfer the embryos into 2ml Dilution Medium 2 (DM-2) for 3 minutes (at this point they will further recover their shape).
8. Transfer the embryos into 2ml Washing Medium (WM). Wash for 3 minutes (at this point, the embryos return completely to their original shape).
9. Transfer the embryos into 2ml WM for 3 minutes.
10. Transfer the embryos into pre-equilibrated culture medium. Allow them to rest in the incubator for two hours before the next step.

