



0241-01

MediCult

Vitrification Cooling

Product No.

1218

Symbols:

Catalogue Number



Batch Code



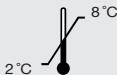
Sterilized using aseptic processing techniques (filtration)



Keep away from sunlight



Temperature limitation
from 2°C to 8°C



Use by



Consult operating instructions



Do not re-use



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MediCult
Innovation with Care

Vitrification Cooling

Intended use

MediCult Vitrification Cooling is for vitrification of human embryos

Composition

Vial 1+2

Plasma protein fraction (Human) 5%, USP

1,2-propanediol

Ethylene glycol

Sucrose

Sodium lactate

Physiological salts

L-glutamine

Sodium bicarbonate

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-I RNA and syphilis. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents

LN₂ may cause freeze burns if in contact with skin and eyes. MediCult recommends that you use gloves and safety goggles.

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

Instructions for use

1. Equilibration Medium (EM) and Vitrification Medium (VM) should be equilibrated to room temperature for at least 30 minutes.
2. Use 1ml in a suitable dish (e.g. 4-well dish) of the medium for the vitrification.
3. Plunge the outer cover of the McGill Cryoleaf™ into the LN₂ bath.
4. Using a suitable pipette, transfer 2-3 embryos to the EM and let them equilibrate for 5 minutes (the embryos initially shrink and then return to their former shape).
5. Transfer the embryos to VM, where they should stay for less than 1 minute (the embryos shrink again).
6. Quickly load the embryos into the McGill Cryoleaf™ tip using the same pipette and as little VM as possible. The McGill Cryoleaf™ should stay dry during the process. Make sure to remove excess VM carefully and quickly using the pipette.
7. Insert the McGill Cryoleaf™ with the embryos directly into liquid nitrogen (LN₂).
8. Carefully slide the protective sleeve (green) over the tip with the embryos and lock it into place by turning. Take care that the McGill Cryoleaf™ remains immersed in LN₂ at all times.
9. Insert the McGill Cryoleaf™ into the outer cover and press tightly. Take care that the McGill Cryoleaf™ remains immersed in LN₂ at all times.
10. Transfer to storage container.

