0246-03

MediCult Vitrification Cooling

Product No.:

1228

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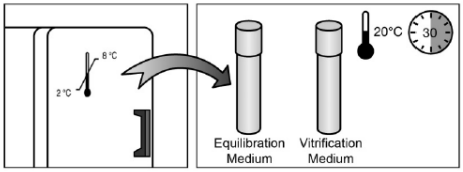
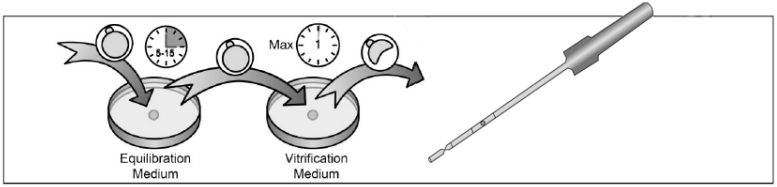
ORIGIO MEDICULT MEDIA





References

Camus et al. 2006. Comparison of the process of five different vitrification devices. Gynecol. Obstet. Fertil. 34, 737-745

Garcia et al. 2010. Initial results of embryo cryopreservation after the introduction of vitrification in a clinical IVF program. Poster presented at CRYO – the 1st International Congress on controversies in cryopreservation of stem cells, reproductive cells, tissue and organs in Valencia, Spain.

Phillips et al. 2010. Prospective observational comparison of traditional slow freezing with a closed vitrification system. Poster presented at ALPHA – 8th Biennial Conference in Budapest, Hungary.

Son et al. 2009. Comparison of survival rate of cleavage stage embryos produced from in vitro maturation cycles after slow freezing and after vitrification. Fert. Stert. 92(3), 956-958.

Balaban et al. 2008. A randomized controlled study of human Day 3 embryo cryopreservation by slow freezing or vitrification: vitrification is associated with higher survival, metabolism and blastocyst formation. Human Reprod., 23, 1976-1982.

Kuwayama et al. 2005. Comparison of open and closed methods for vitrification of human embryos and the elimination of potential contamination. Reprod. Biomed. Online. 11, 608-614.

MediCult Vitrification Cooling

Intended use
MediCult Vitrification Cooling is for vitrification of human day 3 cleavage-stage embryos.

Caution: Federal Law restricts this device to sale by or on the order of a physician or practitioner trained in its use (Rx only).

Caution: The user should read and understand the Directions for Use, Warnings and Precautions, and be trained in the correct procedure before using MediCult Vitrification Cooling and Warming products for vitrification of human day 3 cleavage-stage embryos.

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product were tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material have been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Precautions and warnings
The long term safety of vitrification for children born following this method of embryo cryopreservation is unknown.

Do not use the product if:
1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

Composition
Vials 1 and 2
Human serum albumin (HSA)
1,2-Propanediol
Ethylene glycol
Sucrose
Sodium lactate
Physiological salts
L-glutamine
Sodium bicarbonate
Gentamicin sulphate 10 µg/mL

Quality control testing
Sterility tested (USP).
pH tested (USP) with limits of 7.1-7.5.
Endotoxin tested ≤0.5 EU/mL (USP).
2 cell Mouse Embryo Assay (MEA) ≥80% Blastocysts by 72h.

Osmolality tested (USP) with limits of:
• Vial 1: 941-1001 mOsm/kg in 1:3 dilution
• Vial 2: 1333-1393 mOsm/k in 1:5 dilution

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability
Store in original container at 2-8°C, protected from light.
Do not freeze prior to use.
Discard excess (unused) media following warming.
The product is provided in vials intended for single use.
Do not reuse.
When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Storage device
• Use a legally marketed closed system storage device indicated for use in day 3 cleavage-stage embryo vitrification to prevent the potential risk of viral or other contamination of samples.
• The rate of cooling/warming the storage device should withstand, should be between 1.800°C/min and 20.000°C/min (Camus et al. 2006).

Instructions for use
1. Warm Equilibration Medium and Vitrification Medium to room temperature for at least 30 minutes.
2. Prepare a reservoir with enough liquid nitrogen to allow complete submersion of a goblet on a cryocane. Attach a goblet to the bottom of the cryocane and submerge in the liquid nitrogen. Place near the microscope.
3. Mix the content of the Equilibration Medium and Vitrification Medium vials by a few gentle inversions.
4. Place 1 mL of Equilibration Medium and Vitrification Medium in separate wells or dishes.
5. Using a suitable pipette, transfer 2-3 day 3 cleavage stage embryos into the Equilibration Medium. The cells initially shrink before re-expanding to their original size. Equilibration is completed once the embryos have re-expanded. The equilibration step normally takes 5 – 15 minutes.
6. Transfer the day 3 cleavage-stage embryos in minimum volume into the Vitrification Medium (the embryos shrink again). The time from transfer of the embryos into the Vitrification Medium until vitrified must not exceed 1 minute.
7. Quickly load the day 3 cleavage-stage embryos onto the vitrification carrier and vitrify according to Instructions for Use of the vitrification carrier.
8. Following vitrification, quickly transfer the cryocane and goblet containing the vitrification device and vitrified cells to the storage tank. Make sure that the vitrified cells are submerged under liquid nitrogen at all times.