

MediCult Vitrification Cooling

Product No.:

1228

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Explanation of Symbols (in random order)



Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure



Do not use if package is damaged



Discard excess (unused) media following warming



Indicates the medical device manufacturer



Indicates the manufacturer's batch code so that the batch or lot can be identified



Indicates the date after which the medical device is not to be used



Indicates the manufacturer's catalogue number so that the medical device can be identified



Indicates a medical device that has been manufactured using accepted aseptic techniques



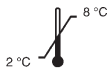
Indicates a medical device that needs protection from light sources



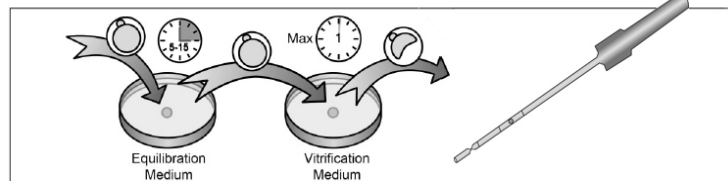
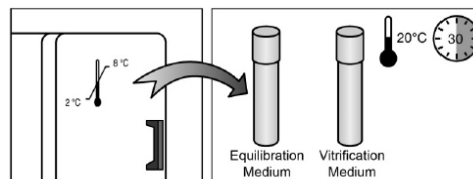
Indicates the need for the user to consult the instructions for use



Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions



Indicates the temperature limits to which the medical device can be safely exposed



MediCult Vitrification Cooling

MediCult Vitrification Cooling is for ultra rapid cooling of human oocytes, cleavage stage embryos, and blastocysts.

This product is for ART treatment, whether the cause of infertility is male or female. The product should only be used by professionals trained in ART treatment.

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)

Endotoxin tested ≤0.5 EU/ml (USP)

2 cell Mouse Embryo Assay (MEA) ≥80%

Blastocysts by 72h

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

Storage instructions and stability

The products are aseptically processed and supplied sterile.

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

Do not freeze.

The product is provided in vials intended for single use.

Excess (unused) media should be discarded.

When stored directed by the manufacturer the product is stable until the expiry 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.

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, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of ART media has not been determined and is still unknown.

Note: Dispose of the device in accordance with local regulations for disposal of medical devices.

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 oocytes or embryos/blastocysts into the Equilibration Medium. The cells initially shrink before re-expanding to their original size. Equilibration is completed once the oocytes or embryos/blastocysts have re-expanded. The equilibration step normally takes 5 – 15 minutes.
6. Transfer the oocytes or embryos/blastocysts in minimum volume into the Vitrification Medium (the cells shrink again). The time from transfer of the oocytes or embryos/blastocysts into the Vitrification Medium until vitrified must not exceed 1 minute.
7. Quickly load the oocytes or embryos/blastocysts 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.