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MediCult Vitrification Warming

Product No.:

1229

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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



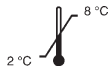
Indicates a medical device that needs protection from light sources



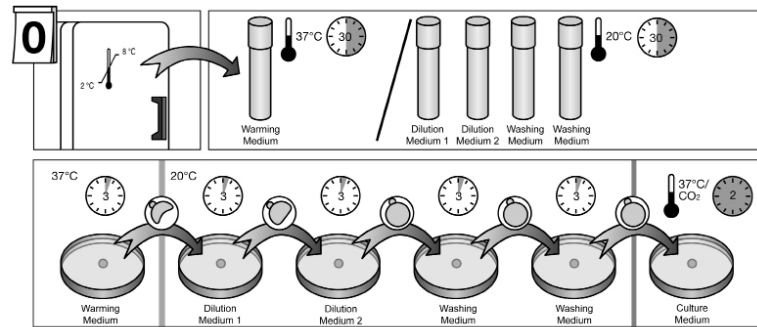
Indicates the need for the user to consult the instructions for use



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 Warming

Vitrification Warming is for warming of vitrified 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, 2, and 3

Human serum albumin (HSA)
Sucrose
Sodium lactate
Physiological salts
L-glutamine
Sodium bicarbonate
Gentamicin sulphate 10 µg/ml

Vial 4:

Human serum albumin (HSA)
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
Vial 4 only: Osmolality tested (USP)

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 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.

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. Pre-warm the Warming Medium to 37°C, and the Dilution Medium 1, Dilution Medium 2 and Washing media 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.
3. Collect the cryocane and goblet containing the carrier device with vitrified oocytes or embryos/blastocysts from the storage container and quickly transfer them to the liquid nitrogen reservoir. Make sure the carrier device remains submerged under liquid nitrogen.
4. Mix the content of the individual vials by a few gentle inversions prior to use.
5. In separate dishes, place 2 ml of Dilution Medium 1, 2 ml of Dilution Medium 2, and 2 x 2 ml Washing Medium.
6. Place 2 ml of Warming Medium at 37°C in a pre-warmed dish just before opening the carrier device according to the manufacturer's instructions for use.
7. Quickly transfer the oocytes or embryos/blastocysts into Warming Medium, and leave them there for a maximum of 3 minutes (at this point, the oocytes or

- embryos/blastocysts are still shrunken).
8. Using a suitable pipette and minimum volume of Warming Medium, transfer the oocytes or embryos/blastocysts into Dilution Medium 1 at room temperature. Leave for 3 minutes (at this point, the oocytes or embryos/blastocysts will start to re-expand).
9. Using a minimum volume of medium, transfer the oocytes or embryos/blastocysts into Dilution Medium 2 and leave them there for 3 minutes (at this point the oocytes or embryos/blastocysts will continue re-expanding).
10. Using a minimum volume of medium, transfer the oocytes or embryos/blastocysts into the Washing Medium and leave them there for 3 minutes. Repeat the washing step by transferring the oocytes or embryos/blastocysts to the final well containing Washing Medium (at this point the oocytes or embryos/blastocysts are fully re-expanded).
11. Transfer the oocytes or embryos/blastocysts into equilibrated culture medium and allow them to rest in the incubator for a minimum of two hours before transfer.