



COLD MEDIUM – 12 vials of 20 ml

Ref: CMXCOLD4RUO

Indication for use : Hypothermic (2-8°C) human corneal storage for 14 days

This product is for Research Use Only (RUO)

1/ INTRODUCTION :

Cold storage of cornea is performed by keeping corneas in a cold storage medium between +2°C and +8°C. Storage in these conditions can last up to 14 days.

Corneas are directly placed in COLD MEDIUM storage medium after surgery, and stored in eye banks between +2°C and +8°C for a maximum of 14 days. The shortest storage time is determined by the time needed to obtain serology results of the donor.

Presentation:

COLD MEDIUM is shipped refrigerated with ice packs. The bottom of the vials is flat and the glass is of hydrolytic class I. This enables the end user to directly visualize and evaluate the quality of the cornea using a slit lamp, without removing the cornea from the storage medium.

Composition / properties:

COLD MEDIUM is a sterile cold storage medium containing:

- Dextran (osmotic agent)
- Essential and non essential amino acids
- Vitamins and electrolytes
- Antibiotics
- Niacinamide
- HEPES and bicarbonate buffers
- Phenol red

pH : 7.25 ± 0.25

Osmolarity = 320 ± 20 mOsm/kg H₂O

Aseptically filtrated medium

2/ REFERENCES :

Description	Reference	Packaging
COLD MEDIUM	CMXCOLD4RUO	12x20 mL

3/ DIRECTIONS FOR USE :

COLD MEDIUM is for hypothermic (2-8°C) human cornea storage for 14 days.

This product is for Research Use Only (RUO).

After surgery and sampling of the cornea, the graft is placed directly into the vial.

Label the vial with a description of the cornea.

Aseptic conditions:

1. Break the seal of the vial and loosen the cap.
2. Lift off the cap and place adjacent to sterile field with inner liner face up.
3. Aseptically transfer cornea and make sure it is submerged in liquid.
4. Tighten the container cap. To ensure integrity, avoid spilling the media into thread areas of the vial and container cap.
5. Cornea can be stored at 2-8°C for up to 14 days.

4/ STORAGE :

COLD MEDIUM is shipped refrigerated in an isotherm box with cold packs. After retrieval of the vials, check the integrity of the vials and keep at +2°C/+8°C.

If the vial is damaged, do not use.

The medium is stable and can be used until the expiration date indicated on the label.

DO NOT FREEZE

5/ RECOMMENDATIONS :

COLD MEDIUM is ready to use. It must not be reconditioned, aliquoted or diluted. The 20 ml volume is the amount necessary for storage of corneas for up to 14 days.

COLD MEDIUM is for single use and cannot be reused.

COLD MEDIUM must not be used for any other applications than the one mentioned in this technical sheet.

COLD MEDIUM is strictly for *in vitro* use. It must not be directly administered to humans for any therapeutic usage.

COLD MEDIUM should only be used by professionals with experience in organ removal.

The medium contains a cherry red indicator. If the colour turns yellow or deep purple (change in pH) or if any turbidity appears, we recommend not using the grafts stored in the medium. Expiration date must be verified.

The medium must be discarded after use in accordance with the usual procedures for the disposal of biological waste.

Any incident or side effect, linked or likely linked to the use of the product should be reported to Eurobio Scientific.

In case of a claim, communicate the lot number to Eurobio Scientific.

6/ WASTE DISPOSAL :

Be in accordance with the law on the elimination of waste of clinical infectious material.

7/ BIBLIOGRAPHY :

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