INTRODUCTION

Cold storage of cornea is performed by keeping corneas in a cold storage medium between +2°C and +8°C. This medium contains Dextran, an osmotic reagent that prevents tissue edema. Storage in these conditions can last up to 21 days. This is very convenient for eye banks with limited staff because of reduced handling of the corneas.

Corneas are directly placed in Cornea Cold® storage medium after surgery, and stored in eye banks between +2°C and +8°C for a maximum of 21 days. The shortest storage time is determined by the time needed to obtain serology results of the donor.

PRESENTATION

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

COMPOSITION / PROPERTIES

Cornea Cold® is a cold storage medium containing
- Dextran
- Essential and non essential amino acids
- Vitamins and electrolytes
- Antibiotics
- Nicotinamide
- HEPES and bicarbonate buffers
- Phenol red

pH : 7.25 ± 0.25
Osmolarity = 320 ± 20 mOsm/kg H2O
Aseptically filtrated medium

INDICATIONS FOR USE

Cornea Cold® is for cold storage of cornea. After surgery and sampling of the cornea, the graft is placed directly into the vial. Cornea Cold® can then be sent to the eye bank in an isotherm box with cold packs for further evaluation according to the protocol of the bank, then stored in a refrigerator between +2°C and +8°C for up to 21 days.

STORAGE

Cornea Cold® 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.

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

RECOMMENDATIONS

Cornea Cold® is ready to use. It must not be reconditioned, aliquoted or diluted. The 28 ml volume is the amount necessary for storage of corneas for up to 21 days. Cornea Cold® is for single use and cannot be reused.

Cornea Cold® must not be used for any other applications than the one mentioned in this technical sheet.

Cornea Cold® is strictly for in vitro use. This product is a class III device according to the 93/42/EEC European directive amended by the 200/47/CE European directive. It must not be directly administered to humans for any therapeutic usage.

Cornea Cold® should only be used by professionals with experience in organ removal.

The medium contains a cherry red indicator. If the color turns yellow or deep purple (change in pH) or if any turbidity appears, we recommend not to use the grafts stored in the medium.

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

REFERENCES

<table>
<thead>
<tr>
<th>Description</th>
<th>Reference</th>
<th>Packaging</th>
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<tbody>
<tr>
<td>Cornea Cold®</td>
<td>CMXCOLD4-UN</td>
<td>12x28ml</td>
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<tr>
<td>Cornea Cold®</td>
<td>CMXCOLD4F</td>
<td>1x28ml</td>
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</table>

BIBLIOGRAPHY

- Parekh M., Amoureux MC, Albrecht C., Fortier D., FBOV., EUROBIO. A quantitative approach to evaluate the overall quality of cornea in cold storage demonstrates that Cornea Cold is superior to Optisol-GS. EuCornea Congress, Milan, September 6th, 7th, 8th 2012.

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Eurobio also offers a range of products for organotypic culture.
Check our website or contact our customer service for more information.

This product is a class III device according to the 93/42/EEC European directive amended by the 200/47/CE European directive. This product is within the frame of medical device vigilance system. Any incident or side effect, linked or likely linked to the use of the product should be reported to the competent authorities of the country in which it has been used.