INTRODUCTION

A corneal transplant is usually carried out in three stages.

Corneas are sampled by in situ excision of the cornea (also known as keratotomy). After restoring the donor's tegumen by means of an eye patch (Ref: EYECYEY00), the graft is placed in a transfer medium, CorneaPrepII® (Ref.: CMXSTA01F) CorneaPrepII® allow a room temperature transport up to 6 days however everything must be done to place the cornea between 31° to 34°C as soon as possible. The use of secure caps (Ref: EYEBCH03) ensures that neither the container nor its contents are tampered with during transport.

Registered tissue banks are responsible for storing the corneas. When the eye bank receives the corneal graft, in its transfer medium, the cornea is placed in a storage medium, CorneaMax® (Ref: CMXST001F) and stored at +31°C ± 1°C for the quarantine period (no more than 30 days). During this period, all the statutory analyses are carried out. Storage of the cornea leads to reversible opacification of the cornea.

After analysing the graft and selecting the recipient, the cornea is placed in a deturgescence medium CorneaJet® (Ref: CMXREL01F). The cornea must be kept in this medium for at least 24 hours to ensure transparency. The medium can then be used to transport the graft within 4 days (including the 24 hours of deturgescence). During transport at ambient temperature, the use of secure caps (Ref: EYEBCH00) ensures that neither the container nor its contents are tampered with.

Laboratoires Eurobio can provide three media, each particularly suitable for one of the above stages:
- CorneaPrepII® for sampling and transport,
- CorneaMax® for storage,
- CorneaJet® for the deturgescence and transfer of corneal grafts.

PRESENTATION

CorneaMax® is supplied in a 120 ml white glass bottle containing 100 ml of medium.

To guarantee that the containers have not been tampered with, they are sealed with tamper-proof caps.

Ref: CMXST001F-1C including:
- 10 x 100 ml bottles of CorneaMax®
- Certificates of analysis and technical specifications.

Remember to order additional caps.

Three types of additional sterile caps in individual "peel-off" sachets should be ordered separately:
- Ref. EYEBCH00-F3 : 10 sterile tamper-proof caps for CorneaMax®
- Ref. EYEBCH01-F3 : 10 sterile caps for suspension
- Ref. EYEBCH02-F3 : 10 sterile caps for medium sampling.

COMPOSITION / PROPERTIES

- Cell culture medium (registered formulation) including:
  - Essential and non-essential amino acids.
  - Australian irradiated foetal calf serum.
  - Vitamins and electrolytes.
  - Penicillin – Streptomycin.
  - HEPES buffer and bicarbonate.
  - Phenol red.
- pH: 7.25 ± 0.25.
- Osmolarity = 320 ± 20 mOsm/kg H₂O
- Controlled level of endotoxins
- Free from mycoplasmas
- Medium sterilised by aseptic filtration

INDICATIONS FOR USE

- CorneaMax® sampling medium is ready to use.
- The medium should be thawed gradually: at 4°C, at ambient temperature or in a bain-marie at 37°C.
- When the sample is received from the laboratory, remove the cornea from the transfer medium (CorneaPrepII®) and place in the storage medium (CorneaMax®). The transfer should take place under a
laminar flow hood and all the usual precautions for cell cultures should be taken.

☐ Once the cornea has been placed in CorneaMax®, close the container with any of the three types of sterile cap in accordance with your normal practice (see the technical specifications of the caps).

☐ The graft is stored in this medium at +31°C ± 1°C for the quarantine period (no more than 30 days). During this period, all the statutory analyses are carried out. Storage of the cornea in this medium leads to reversible opacification.

☐ 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 to use the grafts stored in the medium.

RECOMMENDATIONS

☐ CorneaMax® should only be used for in vitro purposes.

☐ CorneaMax® should only be used by professionals with experience in organ removal.

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

☐ The medium contains antibiotics i.e. penicillin and streptomycin.

☐ The medium contains ingredients of bovine origin. The source of supply has been inspected and controlled free of Transmissible Spongiform Encephalopathy.

CONTRA-INDICATIONS

☐ CorneaMax® storage medium is ready for use. It must not be repackaged, portioned or diluted. The 100 ml volume corresponds to the quantity required to store a cornea for 30 days.

☐ The medium must be thawed gradually. Temperatures in excess of 37°C must be avoided.

☐ Do not re-freeze thawed medium.

☐ Do not insert a foreign body (e.g. suture) between the neck and the cap of the containers, or else these will no longer be sealed.

STORAGE

CorneaMax® has been deep frozen at -20°C and is supplied in isothermic packaging containing dry ice.

Upon receipt of the product, check that the containers are deep frozen and store at -15/-22°C.

Stability: see the Use By date on the label.

Thawing: at ambient temperature or in a bain-marie at 37°C.

Stability after thawing: CorneaMax® can be kept at 4°C for no more than 5 days after opening.

NEVER REFREEZE ANY MEDIUM AFTER THAWING

<table>
<thead>
<tr>
<th>Ref</th>
<th>Description</th>
<th>Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMXSTA01F-AR</td>
<td>CorneaPrep®</td>
<td>10 x 60 ml; 10 eye patches; 10 caps</td>
</tr>
<tr>
<td>EYEBCH03-F3</td>
<td>Tamper-proof cap for CorneaPrep®</td>
<td>10 caps</td>
</tr>
<tr>
<td>EYEC10Y00-F3</td>
<td>Eye patch</td>
<td>10 caps</td>
</tr>
<tr>
<td>CMXST001F-1C</td>
<td>CorneaMax®</td>
<td>10 x 100 ml</td>
</tr>
<tr>
<td>EYEBCH00-F3</td>
<td>Tamper-proof cap for CorneaMax® and Corneajeet®</td>
<td>10 caps</td>
</tr>
<tr>
<td>EYEBCH01-F3</td>
<td>Suspension cap for CorneaMax®</td>
<td>10 caps</td>
</tr>
<tr>
<td>EYEBCH02-F3</td>
<td>Sampling cap for CorneaMax®</td>
<td>10 caps</td>
</tr>
<tr>
<td>CMXREL01F-10</td>
<td>Corneajeet®</td>
<td>10 x 50 ml; 10 caps</td>
</tr>
<tr>
<td>EAUCOL00-C8</td>
<td>Trypan Blue</td>
<td>10 x 2 ml</td>
</tr>
</tbody>
</table>

BIBLIOGRAPHY


Manufacturer
Laboratoires EUROBIO
7 avenue de Scandinavie
91953 Les Ulis Cedex B - France
Tel: 33(0)1.69.07.94.77
Fax: 33(0)1.69.07.95.34
www.eurobio.fr