

CorneaJet®

DETURGESCENCE AND TRANSFER MEDIUM

Ref: CMXREL01F

INTRODUCTION

A corneal transplant is usually carried out in three stages.

□ Corneas are sampled by *in situ* excision of the cornea (also known as keratectomy). After restoring the donor's tegumen by means of an eye patch (Ref: EYCEY00), 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: EYBCH03) 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: CMXSTO01F) 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: EYBCH00) 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

CorneaJet® is supplied in a 60 ml white glass bottle containing 50 ml of medium. To guarantee that the

containers have not been tampered with, they are sealed with tamper-proof caps.

An additional sterile tamper-proof cap is supplied in an individual "peel-off" sachet. This cap should be used to seal the container when the cornea is being transported to the graft center.

Ref : CMXREL01F-10 including

- 10 x 50 ml bottles of CorneaJet®
- 10 sterile tamper-proof caps in individual "peel-off" sachets.
- Certificates of analysis and technical specifications.

COMPOSITION / PROPERTIES

• Cell culture medium (registered formulation) including:

- Dextran.
- Australian irradiated foetal calf serum.
- Essential and non-essential amino acids.
- 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

□ CorneaJet® 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.

□ After analysing the graft and selecting the recipient, the cornea is placed in the CorneaJet® deturgescence medium. 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).

□ Once the cornea has been immersed in CorneaJet®, the container should be sealed with a new tamper-proof cap supplied in an individual sterile pack (cf. technical specifications of caps - Ref: EYBCH00). Take out a cap with the same diameter as the container and place it on the neck of the container, holding it vertically on a flat surface. Close

the container by pressing on the cap and screwing it tight. The container will be hermetically sealed once the tamper-proof ring is on a level with the neck of the container.

□ Sealing the container with a tamper-proof cap ensures that the medium remains sterile until opening. Culturing and transfer should be done under a laminar flow hood and all the usual precautions for cell cultures should be taken.

□ 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.

□ Containers must be kept vertical during transport between the removal centre and the eye bank.

RECOMMENDATIONS

□ CorneaJet® should only be used for *in vitro* purposes.

□ CorneaJet® 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

□ CorneaJet® deturgescence medium is ready for use. It must not be repackaged, portioned or diluted. The 50 ml volume corresponds to the quantity required to store a cornea for 4 days.

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

□ Do not re-freeze a 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

CorneaJet® is supplied as a deep-frozen product in isothermic packaging containing dry ice.

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

Stability before thawing: see the Use By date on the label.

Thawing: gradual, at +4°C, at ambient temperature or in a bain-marie at 37°C.

Stability after thawing: CorneaJet® can be stored at 4°C for 5 days before opening.

NEVER REFREEZE ANY MEDIUM AFTER THAWING

REFERENCES IN THE CORNEA RANGE

| Ref | Description | Packaging |
|--------------|--|---|
| CMXSTA01F-AR | CorneaPrepl® | 10 x 60 ml 10 eye patches 10 caps |
| EYEBCH03-F3 | Tamper-proof cap for CorneaPrepl® | 10 caps |
| CMXSTO01F-1C | CorneaMax® | 10 x 100 ml |
| EYECY00-F3 | Eye patch | 10 caps |
| EYEBCH01-F3 | Suspension cap for CorneaMax® | 10 caps |
| EYEBCH02-F3 | Sampling cap for CorneaMax® | 10 caps |
| CMXREL01F-1O | CorneaJet® | 10 x 50 ml 10 caps |
| EYEBCH00-F3 | CorneaMax® and CorneaJet® tamper-proof cap | 10 caps |
| EAUCOL00-C8 | Trypan Blue | 10 x 2 ml |

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