

TISSUE-C & CORNEALFLOAT

MEDIA FOR CORNEAL CULTURE AT 31°C + CORNEAL FLOAT

ORGAN CULTURE AT 31° C

	TISSUE-C	CORNEALFLOAT
Ingredients	Action	
sodium pyruvate, glucose	energetic sources	low density polyethylene (PE-LD)
amino acids, mineral salts	nutrients	
serum	trophic factors	
penicillin G, streptomycin, amphotericin B	antibiotics/antimycotic mixture	
Hepes, bicarbonate	buffers	
phenol red purified	pH indicator	
water	solubilization of ingredients	
Form	sterile liquid	sterile solid
Volume/Diameter	100 ml	22 mm
Physico-chemical parameters	- hydrogenionic activity (pH): 7.20 - 7.60 pH units - osmolality: 255 - 345 mOsm/kg	not applicable
Bacterial endotoxins	< 0.5 EU/ml	not applicable
Sterilization	aseptic filtration and filling according to EN 556-2 and EN ISO 13408-1	radiation according to EN ISO 11137-1 and EN 556-1
Storage temperature	-25°C / -15°C	room temperature
Expiry date	24 months	60 months
Intended use	media for corneal culture	corneal suspension in corneal storage media
Temperature of actual use	31°C	31°C
Duration of actual use	up to 1 month	up to 1 month
Class	medical device	medical device
Medical device class	III	Is
GMDN code	P36094	P36094
CND code	Q020299	Q020299
MD registration number	242257/R	700927/R
CE mark	CE 0373	CE 0477

Tissue-C is a medium for organ culture of donor cornea at 31°C for up to 1 month, packaged in a bottle with a mouth internal diameter of more than 22 mm to facilitate handling procedures in an aseptic environment, thus minimizing the risk of contamination. Solution contains an antibiotic/antimycotic mixture that warrants an effective protection against bacteria and fungi. The phenol red indicator allows a rapid visualization of pH variations. No media replacement is required during culture. Stability studies showed that alternate freezing-thawing cycles do not alter the physical-chemical properties of the media. CornealFloat is an accessory intended to suspend the cornea in the medium.

Ref.: TIS 001-00

Contents:

- ▶ 12 100ml-vial pack
- ▶ 12 CornealFloat
- ▶ 12 labels for traceability
- ▶ 1 package insert

GS1-128 barcode

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GPS

GAS-PERMEABLE STOPPERS AND ALUMINIUM CRIMPS

ORGAN CULTURE AT 31° C

	GPS	CRIMPS
Ingredients	medical grade silicone rubber	aluminium
Form	solid	solid
Size	32 mm	36 mm
Packaging	pouch	pouch
Sterilization	not sterile	not sterile
Storage temperature	room temperature	room temperature
Expiry date	60 months	60 months
Temperature of actual use	31°C	31°C
Intended use	gas-permeable stopper (accessory to TISSUE-C)	crimp to seal Tissue-C bottle during corneal culture
Class	medical device	not applicable
GMDN code	P36094	not applicable
CND code	Q020299	not applicable
MD registration number	288366/R	not applicable
Medical device class	I	not applicable
CE mark	CE	not applicable

GPS, gas-permeable silicone stopper, is an accessory to Tissue-C, media for organ culture of donor cornea. GPS allows the gas exchange between media and environment, thus optimizing corneal culture.

Aluminium crimps are used to seal the Tissue-C bottle.

They prevent caps from popping out during the organ culture

Ref.: GPS 001-00

Contents:

- 100 silicone stoppers
- 100 aluminium crimps

GS1-128 barcode

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