

CRYO.ON

10 ML SINGLE USE PRODUCT

SOLUTION FOR CRYOPRESERVATION OF HUMAN TISSUES AND CELLS INTENDED FOR TRANSPLANTATION

CRYOPRESERVATION

CRYO.ON	
Ingredients	Action
100% dimethyl sulfoxide (DMSO)	cryoprotecting agent, which protects tissues and cells during storage at cryogenic temperatures
Physical parameters	
Aspect	clear sterile liquid
Purity	≥ 99.9% (tested by GC, GC-MS, NMR)
Microbiological parameters	
Endotoxins	tested according to EP and USP < 0.12 EU/ml < 20 EU/device according to USP
Mycoplasmas	absent (tested according to EP, USP)
Sterilization	
Solution	filtration with 0.1 µm filters and aseptic distribution according to EN 566-2 and ISO 13408-1
External part of the vial	ethylene oxide sterilization according to ISO 11135-1
Ethylene oxide residuals	< 0.01 mg/ml according to EN ISO 10993-7
Packaging	tight-fitted class I amber glass vial with butyl rubber closure in a sterile double pouch
Volume	10 ml
Storage temperature	room temperature
Expiry date	48 months
Intended use	cryopreservation of human cardiovascular tissues, bone, tendons, skin, amniotic membrane, and cells
Class	medical device
CND Code	V9099
MD registration number	228818/R
Medical device class	Ila
CE mark	CE 0546

CRYO.ON is dimethyl sulfoxide (DMSO) with purity higher than 99.9%, which is certified for use with human tissues and cells intended for transplantation. Product is sterile, apyrogenic and mycoplasma-free according to the current Pharmacopoeias (EP and USP). It is packaged in sterile double pouch to meet GMP requirements.

Ref.: CRN 001-00

Contents:

- ▶ 1 vial of 10 ml CRYO.ON in sterile double pouch
- ▶ 4 labels for product traceability
- ▶ 1 package insert

GS1-128 barcode

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