

Cornea Graft Containment Solution

iRestore Conservation, sterile

*Liquid for the preservation
of corneal grafts in
hypothermic conditions up to
14 days*



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iRestore Conservation, sterile
Liquid for the preservation of corneal grafts in hypothermic conditions up to 14 days
INSTRUCTION FOR USE



INTENDED USE

iRestore Conservation, sterile is a device intended for the preservation of corneal grafts in hypothermic conditions, up to 14 days.

QUALITATIVE COMPOSITION

COMPOSITION	FUNCTION
Sodium Pyruvate, Glucose	Energy source
Salts, aminoacids, vitamins	Nutritional sources
Gentamycin, 2-mercaptoethanol	Preservative system
Dextran	Osmotic agent
HEPES and Sodium bicarbonate	pH Buffer
Phenol red	pH indicator

FIELD OF APPLICATION

The device is used along the procedures for cornea transplantation, allowing the preservation of the organ up to 14 days from the removal.

PREVENTATIVE MEASURES

Instruction for use must be carefully followed.

Verify cleanliness and color of the solution before its use and along all the conservation lapse.

DRUGS INTERACTIONS AND OTHERS

Drugs interactions are not known. The device is completely removed before cornea re-implantation.

WARNINGS

Do not use if the device is not intact.

Do not use if the device expired, according to date shown on labels and packaging.

Do not use if the device color turned yellowish.

Use the device only if the solution is clear, free of visible particles.

Store at a temperature in between +2°C and +8°C.

The device must be used immediately after its opening, for not more than 14 days, and must be then maintained at a temperature in between +2°C and +8°C. Can be storage for a short time at room temperature before use.

Single use.

DESCRIPTION AND TECHNICAL SPECIFICATIONS

The device **iRestore Conservation, sterile** – liquid for the preservation of corneal grafts in hypothermic conditions up to 14 days is composed of a plastic flask with a screwcap, containing a particular preservation mixture.

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INSTRUCTION FOR USE

iRestore Conservation, sterile can be used solely by specialized medical personnel.

iRestore Conservation, sterile can be used if the liquid contained is clean, free of visible particles and the packaging is intact.

Perform all the procedures described below in aseptic conditions

(e.g.: laminar flow hood in controlled environment)

1. Remove the warranty seal.
2. Unscrew the cap from the flask.
3. The device is ready to be used.
4. In order to take the cornea from the device, use sterile tools and rinse the organ with at least 100 mL of sterile isotonic solution or sterile water for injection.
5. Proceed following the instructions of the medical equipment.

ADVERSE REACTIONS

If the device is correctly used, side effects are not common.

PACKAGING

Box with 12 flasks of 20 mL each.

Box with 12 flasks of 30 mL each.

Box with 12 flasks of 40 mL each.

MANUFACTURER

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Labelling symbols

Symbol	Meaning
	<i>Read carefully the instruction for use</i>
	<i>Conservation temperature limits</i>
	<i>Keep from light and heat sources</i>
	<i>Sterilized via aseptic techniques</i>
	<i>Single use</i>
	<i>Do not use if damaged</i>
	<i>Lot number</i>
	<i>Reference code</i>
	<i>Manufacturer</i>
	<i>Manufacturing date</i>
	<i>Expiry date</i>
	<i>Medical device conform to EU Directive 93/42/CEE</i>

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