



INSTRUCTIONS FOR USE

**SERVATOR P SALF****STERILE PYROGEN-FREE SOLUTION FOR ORGAN PRESERVATION AND
FLUSHING
NOT INJECTABLE****COMPOSITION**

Dextran 40	50	g	Sodium	138	mmol/l
Glucose monohydrate	1	g	Potassium	6	mmol/l
Potassium chloride	0.4	g	Magnesium	0.8	mmol/l
Sodium chloride	8	g	Glucose	5	mmol/l
Magnesium sulfate heptahydrate	0.201	g	Chlorides	142	mmol/l
Potassium dihydrogen phosphate	0.063	g	Sulfates	0.8	mmol/l
Disodium phosphate dihydrate	0.0576	g	Total Phosphates	0.8	mmol/l
Water for injections q.s. to	1000	ml			

PERFUSION IS INDICATED FOR FLUSHING.

Physical properties: The solution has a calculated osmolarity of about 295 mOsmol/l. pH: 5.3 to 5.5.

TYPE OF DEVICE: Sterile pyrogen-free solution for organ preservation of Class IIa. The solution is clear, colorless or slightly yellow.

INTENDED USE: The solution is used for organ perfusion and hypothermic preservation.

It is an ideal solution for the preservation of vascular grafts, pancreas and lungs.

It may also be used as a base or "carrier" electrolytic solution for other specific organs or active components such as scavengers and immunosuppressants or gene therapy.

The device can only be used by medical staff adequately trained in its use in accordance with established operating protocols.

MECHANISM OF ACTION: The solution cooled to 4° to 8° C (39° to 46° F) is used to spray the organ isolated immediately after removal from the donor.

The colloidal component Dextran 40 protects in particular microvessels from a possible damage caused by the post-ischemic reperfusion, since it prevents pathological leukocyte-endothelial interactions. In addition, Dextran 40 prevents edema and the formation of thrombi.

CONTRAINDICATIONS: Hypersensitivity of the receiver to one or more components of the medical device.

WARNINGS AND PRECAUTIONS FOR USE

- DO NOT USE FOR DIRECT INJECTION OR INTRAVENOUS INFUSION.
- The solution Servator P SALF must only be used for perfusion and cold storage of organs during transplantation.
- Do not use if the solution contains particles. Use only clear colorless or slightly yellow solutions in undamaged containers.
- Before use the pH of the solution should be adjusted to 7.4 by adding a suitable buffer. For that purpose add 25 ml of THAM SALF 1 mMol to 1000 ml of Servator P SALF. The addition must be carried out taking all the usual precautions in order to maintain sterility. Stir well during the preparation and before use.
- After the addition of the buffer, the solution must be cooled and used within 24 hours.
- No need to filter the solution before use.
- The solution is not suitable for hypothermic preservation by continuous mechanical perfusion.
- The device is sterile and disposable. The solution is intended for one uninterrupted administration and any residue must be discarded to avoid risk of contamination due to loss of sterility.

INSTRUCTIONS FOR USE: The amount of solution to be used depends on the type of organ or organs to be preserved.

For the perfusion in lung transplantation 50-75 ml of Servator P SALF per kg of body weight of the donor are used. For an adult donor 3-8 liters of solution are needed.

The correct method of perfusion is related to the adopted protocol and depends on the number of organs removed.

The organ is perfused through a cannula inserted in an artery by applying a pressure sufficient to maintain a constant flow (generally it is sufficient to hang the bag at a height of 30 cm above the organ), until the organ becomes uniformly pale and the flowing solution is clear.

The protocol of hypothermic preservation may differ from a hospital to the other, nevertheless the technique of the triple container is now widely adopted internationally.

The organ removed from the donor is transferred to the transport container, after being placed in a sterile bag containing the solution Servator P SALF cooled to 4° to 8° C (39° to 46° F).

The organ must be completely submerged and covered by the solution. The bag is sealed with adhesive strip or similar device. The bag is placed in a second container, which is also filled with the solution Servator P. In such a way we prevent the isolated organ and its cooling from being compromised due to trapped air pockets.

The organ adequately protected by this double casing is placed in a plastic container sealed with sterile safety cover. At this point, the sealed container is placed in the transport container, which contains ice useful to maintain suitable conditions of temperature during transport.

Documents containing information about the donor, laboratory tests and samples of donor blood are attached to the container.

The transport of the organ preserved in the solution Servator P SALF should be done as quickly as possible.

INCOMPATIBILITIES: No known incompatibilities and interactions, if the device is used as specified.

SIDE EFFECTS: No known side effects. If the solution is used in accordance with the instructions for use, no side effects are expected.

WARNINGS AND PRECAUTIONS IN RELATION TO THE SHELF LIFE OF THE DEVICE

EXPIRY DATE: Check the expiry date printed on the container. The expiry date refers to the unopened product.

WARNING: Do not use the device after the indicated expiry date.

Do not use the solution, even if it is not expired, if visible particles, precipitate or contamination are detected.

After the addition of the buffer, the solution must be cooled and used within 24 hours.

SPECIAL PRECAUTIONS FOR STORAGE: Store below 30°C. Avoid exposure to heat sources. Do not freeze.

Store in its original container. Do not remove the overwrap until immediately before use.

The device is sterile and disposable. The solution must be used for one single uninterrupted administration and any residue must be discarded to avoid risk of contamination due to loss of sterility. Do not use if the solution is frozen.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

NATURE AND CONTENTS OF CONTAINER: Primary container: PVC-free bag, 1000 ml.

SPECIAL PRECAUTIONS FOR HANDLING AND DISPOSAL OF THE DEVICE

Unused residues of the solution and waste materials should be disposed of in conformity with the local regulations.

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