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INSTRUCTIONS FOR USE

# SERVATOR® M SALF

SOLUTION FOR KIDNEYS PERFUSION AND PRESERVATION
STERILE PYROGEN-FREE

**NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION**

REF: SERVM10DMA

## TYPE OF DEVICE

SOLUTION FOR KIDNEYS PERFUSION AND PRESERVATION
clear, colourless or light yellow for single use.
Sterile pyrogen-free solution

## SOLUTION COMPOSITION

| Constituent | g/L | mM/L |
|---|---|---|
| Adenine (free base) | 0.68 | 5 |
| Calcium Chloride dihydrate | 0.068 | 0.5 |
| Dextrose (+) monohydrate | 2 | 10 |
| Glutathione (reduced) | 0.92 | 3 |
| HEPES (free acid) | 2.38 | 10 |
| Hydroxyethyl Starch | 50 | N/A |
| Magnesium Gluconate (hydrate) | 1.18 | 5 |
| Mannitol | 5.4 | 30 |
| Potassium Phosphate (monobasic) | 3.4 | 25 |
| Ribose, D(-) | 0.75 | 5 |
| Sodium Gluconate | 17.45 | 80 |
| Sodium Hydroxide | 0.70 | N/A |

Sterile Water for Injection to 1000 mL

## PHYSICAL PROPERTIES

pH: 7.40 at 20°C
Osmolarity: 300 mOsm/L
mEq/L: $Na^+$ 100; $K^+$ 25.

## INDICATIONS FOR USE

Servator® M SALF Solution is intended to be used for flushing and continuous hypothermic machine perfusion of kidneys at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

## PREPARATION AND ADMINISTRATION

The polypropylene (overbag) outer packaging and the oxygen-absorber bag should be removed before use. As soon as the outer packaging has been removed, the container should be checked for any leaks by squeezing the bag. If a leak is found, the solution must not be used.
Inspect perfusate to ensure there is no particulate matter, precipitates or contamination in the perfusate. If the perfusate is clear and no particulate is observed, the perfusate is safe to use. The solution may turn yellow during storage. This does not impair the quality and effectiveness of Servator® M SALF.
*Note:* If the perfusate contains any particulate, contact Preservation Solutions, Inc to make arrangements to return.
Pre-cool the kidney by vascular flush-out using Servator® M SALF or other cooled solutions (2°- 8°C) (Servator® B, Ringers, or saline).
The kidney can then be placed into a perfusion apparatus that is capable of maintaining temperature within the range of 2 ° - 8 °C.
The kidney should be perfused following the manufacturers or perfusionists protocol. Servator® M SALF is suitable for a mean perfusion time of 29 hours ±8 hours1. Servator® M SALF should be flushed from the donor organ at the time of implantation.
For further information regarding clinical experience with organ preservation solutions, please contact the company for a bibliography of organ preservation articles.

## ADDITIVES

Possible additives: Penicillin (150,000 units), Regular Insulin (40 units) and Dexamethasone (8 mg).

## PRECAUTIONS

Servator® M SALF is made with Hydroxyethyl Starch, which has been the cause of hypersensitivity reactions in patients.
Also, if applicable penicillin, insulin and dexamethasone have caused hypersensitivity reactions in patients.
Physicians should be prepared to respond to possible reactions.

## WARNING

Servator®M SALF may not be used for systemic infusion. This product is NOT intended for direct injection or I.V. use. It is indicated only for selective perfusion of the kidney for the preservation of the donor organ during the transport from donor to recipient.

## ADVERSE REACTIONS

When Servator® M SALF solution is used as described, no adverse reactions attributed to the solution have been observed.

## SPECIAL PRECAUTIONS FOR STORAGE

Store in its original packaging to protect the product from light. Servator® M SALF solution should be stored between 2° - 25°C (35.6° - 77°F). While 5°C is the ideal temperature for actual perfusion of Servator® M SALF, a range of 4 ° - 8°C is acceptable. Do not freeze or expose to excessive heat.

## EXPIRY DATE

Check the expiry date printed on the container. The expiry date refers to the product properly stored in an unopened package.

CAUTION: Do not use after the expiration date. Do not use the solution even before expiration if turbidity, visible particles, precipitate or contamination are detected.
Do not use if the container is damaged.
The solution should be used for a single, uninterrupted administration only and any residue should be discarded to prevent the risk of contamination due to loss of sterility.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

## SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING OF THE DEVICE

Any unused part of the device and waste material deriving from it should be disposed of in accordance with local legislation in force.

## TYPE OF PACKAGING

PVC-free bag containing 1000 ml of solution.
Box of 10 bags.

## MANUFACTURER

S.A.L.F. S.p.A. LABORATORIO FARMACOLOGICO
Via Marconi, 2
24069 Cenate Sotto
Bergamo - Italy

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured by:
S.A.L.F. S.p.A. LABORATORIO FARMACOLOGICO
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For:
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