




# SERVATOR® P

Medical device
CE 0373

**Sterile, pyrogen-free solution**
**Class III**

## DESCRIPTION

The solution is used for organ flushing and hypothermic preservation.

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

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

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.

## AVAILABLE IN THE FOLLOWING PACKAGING:

**Servator® P + THAM**

- box of 5 bags 1000ml +5 vials THAM
- box of 2 bags of 3000ml + 2 vials of THAM (available only for U.S. market)

## SHELF LIFE

24 months.
Storage is +2°C / +30°C and protect from light.

## PHYSICAL PROPERTIES:

Sterile pyrogen-free solution
for organ preservation of Class III.

The solution is clear, colorless or slightly yellow.

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

## SERVATOR® P SALF

Solution is indicated for hypothermic preservation of preservation of Vascular grafts, Pancreas and Lungs.

- Useful for riperfusions
- No filtration required
- Extra cellular action
- Final sterilization: sterility and pirogen free warranty



# SERVATOR® M

Medical device CE 0373

**Sterile, pyrogen-free solution**
**Class III**

## DESCRIPTION

The Servator® M Solution is intended for rinsing and hypotermic preservation of kidney.

This product is made up of electrolytes and nutrients and has a dual purpose:

1) Prevent the action of energy consumption process;

2) Mimic the composition of the cellular fluid on order to keep the tissues vital and satisfy the organ's cellular need for the entire storage time.

The Servator® M Solution has no systemic activity, as its use is limited to organ preservation before the transplant procedure.

The ideal temperature for use of the medical device is +5°C; however, use between +2°C and +8°C is acceptable.

The cooled solution does not come into direct contact with the donor patient but with the suitably isolated organ.

Servator M® Solution must be flushed from the donor organ at the time of implantation.

The Servator® M Solution can be used only by medical staff properly trained to its use, in accordance with established operating protocols.

## AVAILABLE IN THE FOLLOWING PACKAGING:

**Servator® M**

- Box containing 10 bags of 1000 ml.

## SHELF LIFE

24 months
Storage is between +2°C/+25°C and protect from light.

## PHYSICAL PROPERTIES:

The Solution is clear, colorless, or slightly strawyellow solution.

**pH:** 6.90 ÷ 7.50

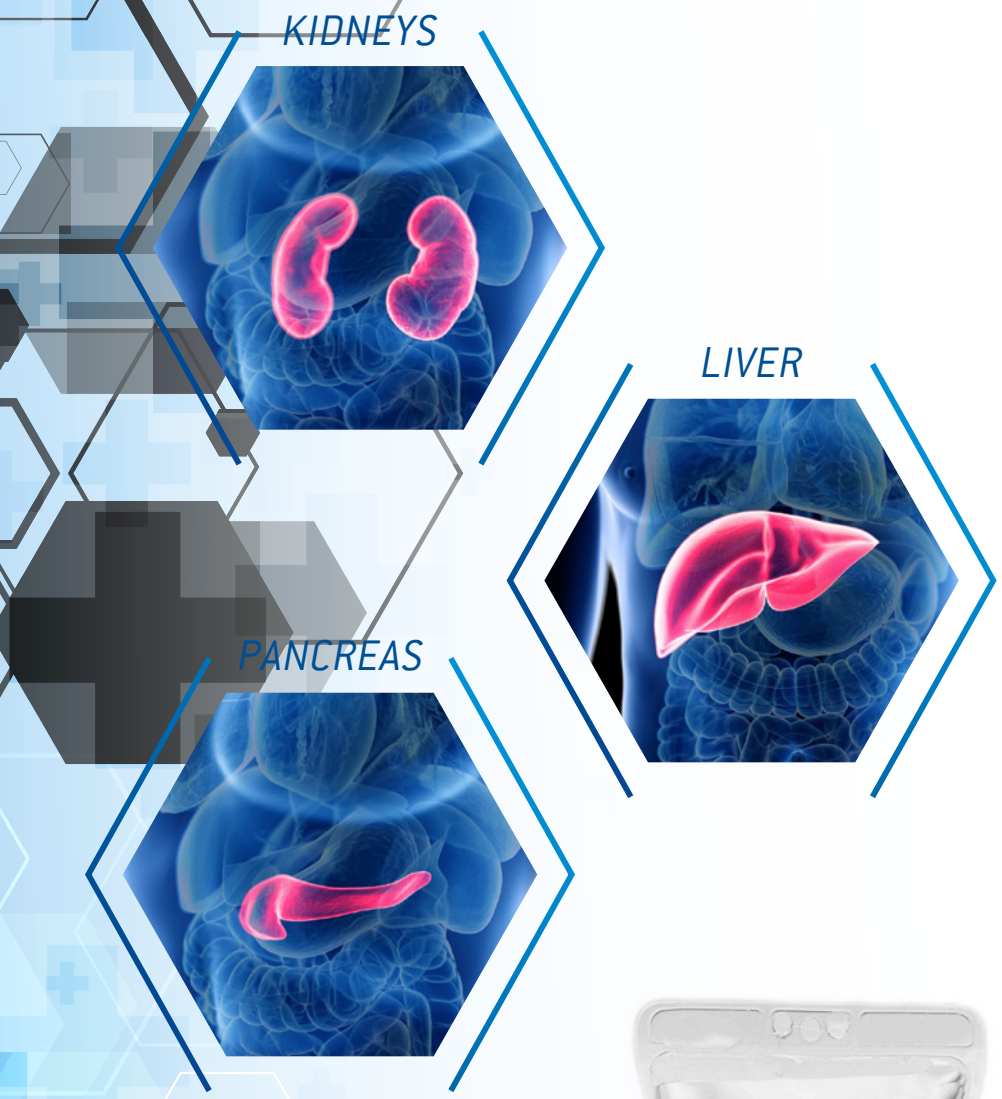
**Osmolarity:** 270.00 ÷ 330.00 mOsm / Kg

**NOT INTENDED FOR SYSTEMIC ADMINISTRATION BY DIRECT INJECTION OR INTRAVENOUS INFUSION.**
**Read carefully the package leaflet before use.**

## SERVATOR® M SALF

Solution is indicated for hypothermic preservation of kidney.

- Useful for riperfusions
- No filtration required
- Extra cellular action
- Final sterilization: sterility and pirogen free warranty





# SERVATOR® B

Medical device
CE
0373

**Sterile, pyrogen-free solution**
**Class III**

## DESCRIPTION

The Servator® B Solution is intended for flushing and hypothermic preservation of kidney, liver and pancreas.

This product is designed to reduce the metabolism and the oxygen demand of the organ and is able to extend storage time by minimizing the intrinsic damage of ischemia and reperfusion. It is made up of electrolytes and nutrients and has a dual purpose:

1) Prevent the action of energy consumption process;

2) Mimic the composition of the cellular fluid on order to keep the tissues vital and satisfy the organ's cellular need for the entire storage time.

At a temperature of 2 - 6°C, Servator® B Solution is used to flush the isolated organ immediately before or immediately after removal from a dead donor or immediately after removal from a living donor.

The Solution remains in the organ vessels during hypothermic storage and transportation.

The device should be used for the cold storage of the organ and it is not suitable for the hypothermic preservation with a continuous machine perfusion.

The Servator® B Solution can be used only by medical staff properly trained to its use, in accordance with established operating protocols.

## AVAILABLE IN THE FOLLOWING PACKAGING:

**Servator® B**
- Box containing 10 bags of 1000 ml.
- Box containing 5 bags of 2000 ml.

## SHELF LIFE

24 months
Storage is between +2°C/+25°C and protect from light.

## PHYSICAL PROPERTIES:

The Solution is clear and colorless, or light yellow.

The Solution has a calculated osmolarity of about 320 mOsm / Kg.

**pH:** 7.4 at 20°C
**Sodium Concentration:** 29 mEq / L
**Potassium Concentration:** 125 mEq / L.

**NOT INTENDED FOR SYSTEMIC ADMINISTRATION BY DIRECT INJECTION OR INTRAVENOUS INFUSION.**
**Read carefully the package leaflet before use.**

## SERVATOR® B SALF

Solution is indicated for hypothermic preservation of kidney, liver and pancreas.
- Useful for riperfusions
- No filtration required
- Intra-cellular action
- Final sterilization: sterility and pirogen free warranty



# SERVATOR® P plus

Sterile, pyrogen-free solution
Class II

## DESCRIPTION

Servator P Plus is an extracellular electrolyte solution containing Dextran 40. The solution is pre-buffered with 2 mM THAM and pre-supplemented with 0.5 mM CaCl2. Servator P Plus is used for rapid cooling, perfusion and cold static storage of lungs in connection with transplantation.

Administration of the solution at the recommended temperatures will effectively cool the lung to reduce its metabolic requirements.

The colloid component, Dextran 40 counteracts tissue oedema and protects the microvasculature against post-ischaemic reperfusion injury.

Calcium is important to maintain endothelial and epithelial cell integrity and endothelial contractility. The device is buffered with THAM to achieve a physiological pH.

Servator P Plus enables safe preservation of lungs for up to 12 hours depending of status of the lung during retrieval.

The intended patient population is adult patients in need of a lung transplantation.

## AVAILABLE IN THE FOLLOWING PACKAGING:

**Servator® P plus**

- Box containing 10 bags of 1000ml.
- Box containing 3 bags of 3000ml.

## SHELF LIFE

24 months
Storage is between +2°C/+25°C and protect from light.

## PHYSICAL PROPERTIES:

Sterile pyrogen-free solution for organ preservation FDA approved.

The solution is clear, colorless or slightly yellow.

P Plus is a  buffered, calcium containing solution for lung preservation.

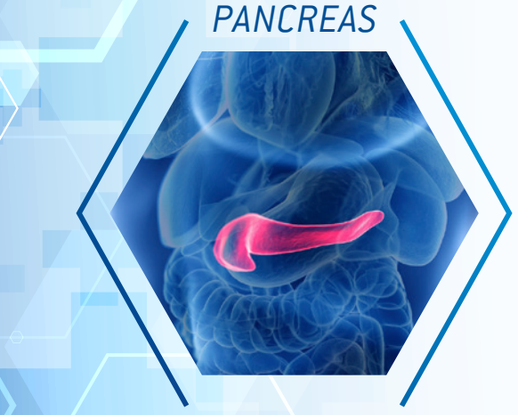
The solution has a calculated osmolarity of about 295 mOsmol/l. pH: 7.20 to 7.60.

## SERVATOR® P plus SALF

Solution is indicated for hypothermic preservation of lungs.

- Useful for riperfusions
- No filtration required
- Extra cellular action
- Final sterilization: sterility and pirogen free warranty







*Also used for Vascular grafts

# SERVATOR® H

Medical device CE 0373

## Sterile, pyrogen-free solution
## Class III

## DESCRIPTION

The device is used for the preservation of organs with venous or arterial segments for the transplant: heart, kidney, liver, pancreas.

The Servator® H prolongs the ischemic tolerance of the organ subjected to protection with two mechanisms:

1. The energy demand by the protected body is reduced to minimum possible levels thanks to the electrolytic composition of the solution;

2. The production of anaerobic energy is limited in the inhibition of glycolysis due to decrease in pH resulting from the accumulation of lactic acid;

During the procedure, cold ischemia inevitably occurs when the organ is removed to the donor's body and placed in ice and lasts as long as the organ is preserved.

Hypothermia is an essential factor for the organs' protection and is obtained by flushing the organ through the artery with Servator® H.

It is a cold solution that contains electrolytes and nutrients useful to support the cellular needs of the organ that is found temporarily housed in a transport system.

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

## AVAILABLE IN THE FOLLOWING PACKAGING:

**Servator® H**
- Box containing 10 bags of 1000 ml.
- Box containing 5 bags of 2000 ml.
- Box containing 2 bags of 5000 ml.
- Box containing 1 vial of 100 ml.*

## SHELF LIFE

18 months
Storage is between +2°C/+8°C and protect from light.

## PHYSICAL PROPERTIES:

The Solution is clear and colorless, or light yellow.
**pH:** 7,02 - 7,20 a 25°C; 7,40 - 7,45 a 4°C;
**Osmolarity:** 310 mOsm/Kg.

**NOT INTENDED FOR SYSTEMIC ADMINISTRATION BY DIRECT INJECTION OR INTRAVENOUS INFUSION.**
**Read carefully the package leaflet before use.**

## SERVATOR® H SALF

Solution is indicated for hypothermic preservation of kidney, liver, pancreas, heart and vascular grafts.
- Useful for riperfusions
- No filtration required
- Extra cellular action
- Final sterilization: sterility and pirogen free warranty



# SERVATOR® C

Medical device
CE
0373

**Sterile, pyrogen-free solution**
**Class III**

## DESCRIPTION

Servator® C Solution is a clear to light yellow, single use only, sterile (by steam sterilization) and pyrogenfree for hypothermic cardiac flushing and storage in preparation for transportation and eventual transplantation of thoracic organs, as heart and lung, as well as abdominal organs, as kidney, liver, and pancreas, during transplantation.

The Servator® C Solution is designed to reduce metabolism and oxygen demands of the organ and is able to extend storage time by minimizing the intrinsic damage of ischemia and reperfusion. It is made up of electrolytes and nutrients and has dual purpose:

1) Prevent the action of energy consumption process;

2) Mimic the composition of the cellular fluid on order to keep the tissues vital and satisfy the organ's cellular need for the entire storage time.

At a temperature of 2°C - 8°C (36°F - 46°F), Servator® C Solution is used to flush the isolated organ immediately before/after removal from a dead donor or closely after removal from a living donor.

The use of this medical device at the recommended temperatures allows an effective cooling of the organ.

The Solution remains in the organ vessels during hypothermic storage and transportation.

The Servator® C Solution can be used only by medical staff properly trained to its use, in accordance with established operating protocols.

## AVAILABLE IN THE FOLLOWING PACKAGING:

**Servator® C**
- Box containing 10 bags of 1000 ml.

## SHELF LIFE

24 months
Storage is between +2°C/+25°C and protect from light.

## PHYSICAL PROPERTIES:

TThe Solution is clear and colorless, or light yellow.

The Solution has a calculated osmolarity of about 242 - 368 mOsm / Kg.

**pH**: 7,3±0,2 at 20°C

**NOT INTENDED FOR SYSTEMIC ADMINISTRATION BY DIRECT INJECTION OR INTRAVENOUS INFUSION.**
**Read carefully the package leaflet before use.**

## SERVATOR® C SALF

Solution is indicated for hypotermic preservation of kidney, liver, pacreas, lungs and heart.
- Useful for riperfusions
- No filtration required
- Extra cellular action
- Final sterilization: sterility and pirogen free warranty