



SALF

Medical
device



SERVATOR RANGE
ORGAN PRESERVATION SOLUTION



S.A.L.F.

OUR HISTORY YOUR HEALTH

WHO WE ARE

Since 1921 S.A.L.F. S.p.A. Pharmacological Laboratory has been producing in its own factory in Cenate Sotto (BG) sterile solutions for injections for hypodermoclysis/phlebotoclysis, parenteral nutrition, irrigation, dialysis, anticoagulant solutions, solutions for organ preservation, anesthetics, analgesics, markers and many other drugs, thus covering a wide range of therapeutic categories.

The entire range is produced by the pharmaceutical laboratory in the following forms:

- glass ampoules
- syringes
- glass and polypropylene bottles
- PVC and polypropylene bags

S.A.L.F. S.p.A. is also authorized to produce both medical devices and veterinary drugs in the same dosage forms described above.

AUTHORIZATIONS

All products comply with the standards assigned by the Ministry of Health for the production of drugs and everything is aimed at ensuring their absolute reliability and safety, given the delicate nature of their use. S.A.L.F. pharmacological laboratory has prepared a series of

tests to be performed both on incoming drug substances, that should be analyzed to verify they match with what certified by the supplier, and on finished products, that are subjected to strict analysis before being placed in the distribution network. For that purpose, we make use of an innovative manufacturing plant, characterized by adequate and modern production and control equipment, suitable departments and laboratories and cutting edge manufacturing processes constantly improved.

OUR HISTORY

S.A.L.F. S.p.A. Laboratorio Farmaceutico was founded on August 25, 1921. S.A.L.F. stands for 'Anonymous Pharmacological Laboratory Company' and it was originally a private enterprise that was among the first companies to study the curative properties of the aqueous solutions and to develop a whole wide range of injectables for hospital use. The manufacturing site, which used to be located in the center of Bergamo, at the end of 1960's moved to Cenate Sotto and decided to focus its production on the injectable, irrigation and dialysis solutions. Today the production plant covers 14000 square meters of production departments, labs, warehouses, and offices.

VALUES AND GOALS

S.A.L.F.'s long tradition is committed to health, safety, and environment while remaining focused on Italian pharmaceutical excellence. We provide high quality solutions for specific requirements of each of our clients around the world. Building a long lasting partnership with our clients and relationship with our employees is an integral part of our corporate values. In S.A.L.F., we believe in a corporate model where our clients and our employees are the fundamental part of our extended family and where our employees are being trained to become professionals in the nation-leading company.

MISSION

Development and production of drugs and medical devices in sterile solutions through ongoing research, also customized according to customer needs, meeting the highest quality standards and ensuring a timely and accurate service.

VISION

To be a national forefront in pharmaceutical production and the most valued company to our stakeholders while supporting lives around the world. Use long tradition brimful of flexibility, and experience and incorporate it with innovation that will empower us to be at offer vanguard of health care and well-being products.

CORPORATE SOCIAL RESPONSIBILITY

Taking the right choice every day by participating in activities that benefit society. We are putting a great effort to be a responsible citizen in communities where we are present by incorporating social and environmental priorities.

Environmental efforts: We are implementing sustainability standards and certifications into our company. In 2011 we have installed a photovoltaic plant to reduce the energy needs and we are maximizing our efforts to use recyclable materials when possible. Being responsible today to create better tomorrow.

Philanthropy: donation on both national and international level with a purpose of creating a vibrant community and stable business environment.

Ethical labor practices: S.A.L.F. is still a family owned company and our goal is for our Human Resources to work in family environment. That also means we treat everybody equally and with the respect as well as that we take care of safety conditions at work.

MADE IN ITALY

Located in the industrial heart of Europe, S.A.L.F. takes very seriously the pride of Italian made products. Quality is the best safeguard of Italian tradition and in S.A.L.F., quality goes beyond intangible meaning. Incoming raw materials are carefully controlled and selected. We guarantee rigorous regulation over processes and every stage of production until the final product is finished. Also, our whole production process is certified by internationally recognized bodies. In addition to all mandatory certifications, we are also in possession of certificate of quality management system (ISO 9001), environmental management system (ISO 14001) and medical device quality management system (ISO 13485).

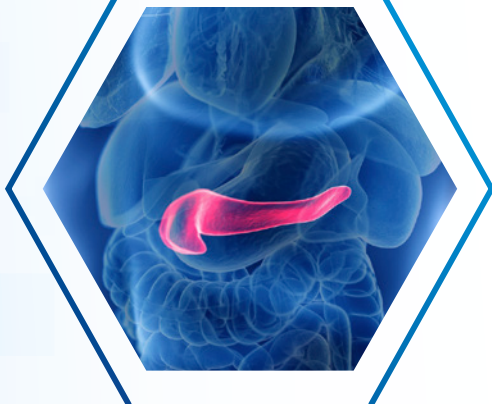
EXPORT COUNTRIES



LUNGS



PANCREAS



SERVATOR® P

Sterile, pyrogen-free solution
Class III

Medical device
CE
0373

SERVATOR® P

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 SALT

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 pyrogen free warranty



KIDNEYS



SERVATOR® M

Sterile, pyrogen-free solution
Class III

Medical
device
CE
0373

SERVATOR® M

DESCRIPTION

The Servator® M Solution is intended for rinsing and hypothermic 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 in 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 SALT

Solution is indicated for hypothermic preservation of kidney.

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



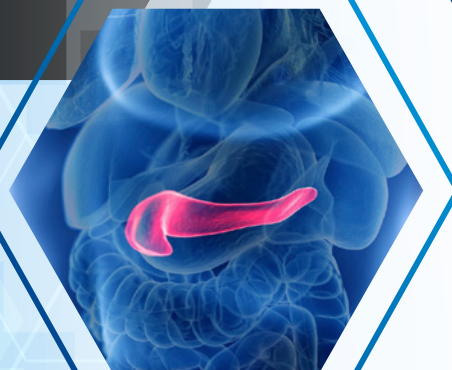
KIDNEYS



LIVER



PANCREAS



SERVATOR® B

Sterile, pyrogen-free solution
Class III

Medical device
CE
0373

SERVATOR® B

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 reperfusion
- No filtration required
- Intra-cellular action
- Final sterilization: sterility and pyrogen 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 osmolality 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



KIDNEYS



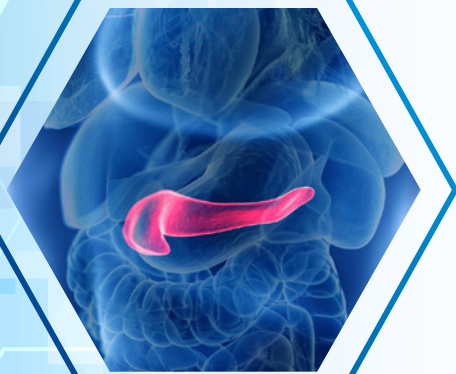
LIVER



HEART



PANCREAS



SERVATOR® H

Sterile, pyrogen-free solution
Class III

Medical device
CE
0373

SERVATOR® H

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 reperfusion
- No filtration required
- Extra cellular action
- Final sterilization: sterility and pyrogen free warranty

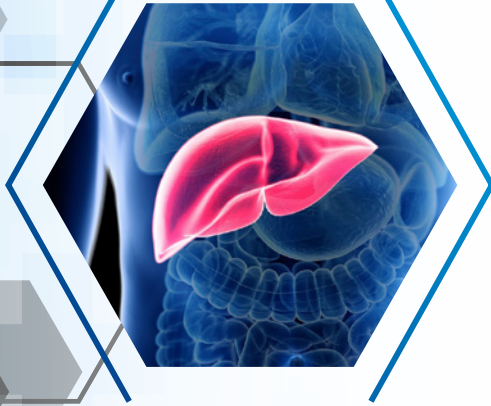
*Also used for Vascular grafts



LUNGS



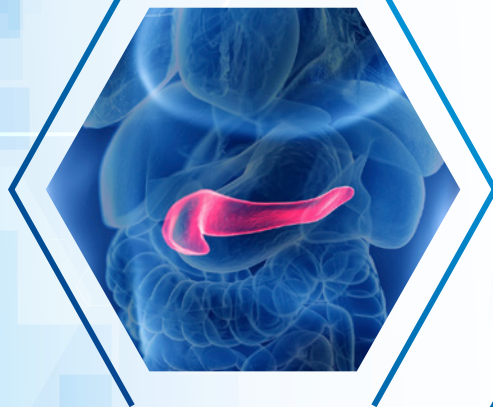
LIVER



HEART



PANCREAS



KIDNEYS



SERVATOR® C

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:

The 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 hypothermic preservation of kidney, liver, pancreas, lungs and heart.

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

Headquarters and production site in Cenate Sotto - Bergamo - Italy



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