



Organ Recovery
systems

SPS-1[®]

(UW Solution)

Static Preservation Solution

Instructions for Use



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INDICATIONS FOR USE

SPS-1 (UW® Solution) is intended for the flushing and cold storage of kidney, liver, and pancreas organs at the time of organ removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

DEVICE DESCRIPTION

Having the same composition as Belzer UW® Cold Storage Solution as originally formulated by F. O. Belzer M.D.* and James Southard, Ph.D.* at the University of Wisconsin® for flushing and cold storage of kidney, liver, and pancreas organs.

SPS-1 (UW Solution) is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution has an osmolality of 310 ± 15 mOsm/kg, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of 7.4 ± 0.1 at 20°C.

SOLUTION COMPOSITION

Constituents	Amount / 1000 mL	Concentration mM
Hydroxyethyl Starch (HES)	50 g	n/a
Lactobionic Acid (as Lactone)	35.83 g	100
Potassium Phosphate monobasic	3.4 g	25
Magnesium Sulphate heptahydrate	1.23 g	5
Raffinose pentahydrate	17.83 g	30
Adenosine	1.34 g	5
Allopurinol	0.136 g	1
Glutathione (reduced form)	0.922 g	3
Potassium Hydroxide	5.61 g	100
Sodium Hydroxide	1.16 g	29
Potassium Hydroxide/Hydrochloric Acid	Adjust to pH 7.4	n/a
Sterile Water for Injection (SWI)	To 1000 mL Volume	To 1000 mL Volume

INSTRUCTIONS FOR USE

SPS-1 (UW Solution) must be cooled to 2–6°C (36–43°F) prior to use. The cold solution is used to flush the isolated organ immediately before removal from the donor and/or immediately after removal from the donor. The solution is then left in the organ vasculature during hypothermic storage and transportation.

1. Remove clear overwrap.
2. Carefully open the clear pouch, being careful not to damage or tear the solution bag.



WARNING: If the solution bag is damaged, discard solution.

3. Perform a visual inspection of the solution and ports and check for leaks.



WARNING: Do not use if there is evidence of contamination, particulates or precipitates in the solution or the ports or if a leak is evident. Contact Organ Recovery Systems to make arrangements to return solution.

4. Remove the cap from the Delivery Port.
5. Insert administration set into the Delivery Port with a twisting motion.

NOTE: Glutathione, one of the components of SPS-1 (UW Solution), oxidizes during storage. If desired, an additional 0.922 g/L (3 mmole/L) of glutathione may be added if Transplant Center policy or Surgical Personnel requirements call for its use. (Boudjema et al. *Transpl. Proc.* 1991; Merion et al. *Transpl. Proc.* 1991).

6. Prior to connection to the organ, suspend the solution bag from a sufficient height to allow for a steady stream of solution and to produce flow rates of at least 30 mL/min. during flushing.
7. Squeeze the administration set drip chamber until half full of solution. Open administration set clamp to purge tubing of air. Close clamp until ready to dispense solution.

NOTE: Flushing should continue until the organ is uniformly pale and the effluent is relatively clear. The suggested minimum perfusate volume is as follows:

In situ aortic flush:

Adults, 2-4 L
Infants, 50 mL/kg

Ex vivo infusion:

Liver (via portal vein and biliary tree):
Adults, 1200 mL
Infants, 50 mL/kg

Pancreas or Kidney:
Adults, 300-500 mL
Infants, 150-250 mL

NOTE: For cold storage, additional solution should be dispensed into the container holding the organ. The organ storage container should be sealed aseptically and should be maintained within a well-insulated transport container. Ice should be used to surround the organ storage container, but should not be used within the container.

NOTE: In order to minimize residual solution in the liver, just prior to anastomosis, flush one Liter of Lactated Ringer's through the hepatic portal vein.



WARNING: Donor organs must be flushed free of SPS-1 (UW Solution) prior to anastomosis to prevent potentially serious cardiovascular complications such as hyperkalemic cardiac arrest or bradyarrhythmia in the recipient.



WARNING: SPS-1 (UW Solution) is to be used for cold storage of the organ and is not acceptable for continuous machine perfusion.

ISCHEMIA TIMES

The recommended ischemia times for each organ are:

	Cold Ischemia Times		Warm Ischemia Times
Liver	not longer than 17 hours	Liver	not longer than 2.5 hours
Kidney	not longer than 23 hours	Kidney	not longer than 2.5 hours
Pancreas	not longer than 21 hours	Pancreas	not longer than 2.5 hours

NOTE: These are recommendations. As part of your clinical practice, please follow your organization's clinical guidance on ischemic times.

STORAGE CONDITIONS

Store between 2°C and 25°C (36°F and 77°F). Do not freeze and avoid excessive heat. Keep dry and keep away from direct sunlight. Sterile unless solution bag is damaged or open.

SHELF LIFE

The shelf life for an unopened bag is 2 years. Solution should be used immediately after opening in accordance with specific perfusion center protocol.

CONTRAINDICATIONS

There are no known contraindications when used as directed.

ADVERSE REACTIONS

Cardiovascular complications such as bradyarrhythmia have been reported in cases where the organ has been reflushed with fresh solution within a short period (1 to 3 hours) prior to the release of vascular anastomosis clamps in the recipient, or when inadequate flush of the solution has occurred.

A few anecdotal reports when this solution was used in liver graft preservation described clinical problems including hepatic functional changes, poor outcomes including death, and biopsies showing ischemic damage in the liver with or without signs of mild rejection.

SPS-1 (UW Solution) includes components (allopurinol and pentafraction) which individually have caused hypersensitivity in patients. Physicians should be alert to treat possible reactions.

TECHNICAL ASSISTANCE

Please contact Organ Recovery Systems 24/7 Perfusion Helpline at +1.866.682.4800 (toll free in US), +32.2.715.0005 (Belgium), +1.352.721.5301 (Central and South America), or +33.9.6723.0016 (France).

WARNINGS AND PRECAUTIONS

- R_{Only}** **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.
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-  **CAUTION:** SPS-1 (UW Solution) should be stored indoors in a dry location out of direct sunlight.
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-  **WARNING:** Do not use if frozen, cloudy, or exposed to extreme heat.
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-  **WARNING:** Do not use if there is evidence of contamination, particulates, or precipitates in the solution or the ports. Contact Organ Recovery Systems to make arrangements to return solution.
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-  **WARNING:** Not intended for direct injection or intravenous infusion.
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-  **WARNING:** Donor organs must be flushed free of SPS-1 (UW Solution) prior to anastomosis to prevent potentially serious cardiovascular complications such as hyperkalemic cardiac arrest or bradyarrhythmia in the recipient.
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-  **WARNING:** SPS-1 (UW Solution) is to be used for cold storage of the organ and is not acceptable for continuous machine perfusion.
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-  **WARNING:** For single use only. Do not reuse, reprocess or resterilize. Reusing, reprocessing, or resterilization of single-use devices creates a potential risk of patient or user infections due to contamination. This contamination may lead to injury, illness, or other serious patient complications. Discard any unused portion.
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-  **WARNING:** Use standard aseptic technique and universal precautions (e.g., gloves, masks, gowns, goggles or equivalent eye protection, biohazard bags) when handling the kidney, and when handling and disposing of LifePort Kidney Transporter Disposable Products and perfusate to prevent the possible transmission of pathogens to medical personnel and patients. The single practitioner working alone must pay special attention to maintain these conditions.
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EXPLANATION OF SYMBOLS

	Warning/Caution		Use By, YYYY-MM-DD		Temperature Limits
	Lot Number		Manufacturer		Consult Instructions for Use
	Reference Number		Do Not Resterilize		Keep Away From Sunlight
	Do Not Reuse		Medical Device		Keep Dry
	Country of Origin		Single Sterile Barrier System		Prescription Medical Device
	Sterile Medical Devices Using Aseptic Technique (Aseptic Fill)				

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