

# SPS-1<sup>®</sup>

## Static Preservation Solution

## DIRECTIONS FOR PREPARATION AND USE

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

### DESCRIPTION

SPS-1 Static Preservation Solution composition is:

Pentafraction	50	g/L
Lactobionic Acid (as Lactone)	35.83	g/L
Potassium Phosphate monobasic	3.4	g/L
Magnesium Sulfate heptahydrate	1.23	g/L
Raffinose pentahydrate	17.83	g/L
Adenosine	1.34	g/L
Allopurinol	0.136	g/L
Total Glutathione	0.922	g/L
Potassium Hydroxide	5.61	g/L
Sodium Hydroxide/Hydrochloric Acid	Adjust to pH 7.4	
Water for Injection	q.s.	

SPS-1 is a clear to light yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of organs. The solution has an approximate calculated osmolarity of 320 mOsm, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of approximately 7.4 at 20°C.

### ACTIONS

**SPS-1 must be cooled to 2° to 6°C (36° to 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. SPS-1 is to be used for cold storage of the organ and is not acceptable for continuous machine perfusion. Administration of SPS-1 at the recommended temperature, will effectively cool the organ and lower its metabolic requirements.

### INTENDED USE

SPS-1 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.

#### CONTRAINDICATIONS

There are no known contraindications when used as directed.

#### WARNINGS

NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION.

### PRECAUTIONS

The donor organ must be flushed free of the SPS-1 prior to the reperfusion. The organ must be flushed with physiological solution to prevent occurrence (in the recipient) of potentially serious cardiovascular complications such as hyperkalemic cardiac arrest or bradyarrhythmia. This is necessary because of the high concentration of potassium in the solution. These precautions must be taken prior to re-implantation (or transplantation) to avoid cardiac arrest in the recipient.

SPS-1 includes components (allopurinol and pentafraction) which individually have caused hypersensitivity reaction in patients. Additionally, the additives recommended for use with SPS-1 (penicillin, insulin, and dexamethasone) have individually been associated with hypersensitivity reactions in patients. Physicians should consult individual drug labeling and be alert to treat possible reactions.

### 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 release of vascular anastomosis clamps in the recipient, or when inadequate flush-out 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.

### PREPARATION AND ADMINISTRATION WITH LIVER, KIDNEY AND PANCREAS

Cool the solution to 2° to 6°C (36° to 43°F). Remove overwrap prior to use. Check each bag for leaks by squeezing the container firmly. If a leak is found, discard solution container. With the overwrap removed, perform a visual inspection of the solution for particulate matter. Do not use the solution if obvious particulate matter, precipitates, or contamination are evident in the solution.

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