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Organ Recovery
systems

KPS-1®

Kidney Perfusion Solution

Instructions for Use

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INDICATIONS FOR USE
KPS-1, Kidney Perfusion 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.

DEVICE DESCRIPTION
KPS-1, Kidney Perfusion Solution (having the same composition as UW® Machine Perfusion Solution*) is a clear, sterile, non-pyrogenic, non-toxic solution for the in-vitro flushing and temporary continuous perfusion preservation of explanted kidneys. This solution has an osmolality of 300 ± 15 mOsm/kg, a sodium concentration of 100 mEq/L, a potassium concentration of 25 mEq/L, and a pH of 7.4 ± 0.1 at room temperature. Based on the sodium/potassium ratio, the composition is thus consistent with that of an extracellular solution.

SOLUTION COMPOSITION

Constituents	Amount/1000 mL	Concentration, mM
Calcium chloride (dihydrate)	0.068 g	0.5
Sodium hydroxide	0.70 g	
HEPES (free acid)	2.38 g	10
Potassium phosphate (monobasic)	3.4 g	25
Mannitol (USP)	5.4 g	30
Glucose, beta D (+)	1.80 g	10
Sodium gluconate	17.45 g	80
Magnesium gluconate D (–) gluconic acid, hemimagnesium salt	1.13 g	5
Ribose, D (–)	0.75 g	5
Hydroxyethyl starch (HES)	50.0 g	n/a
Glutathione (reduced form)	0.92 g	3
Adenine (free base)	0.68 g	5
Sterile water for injection (SWI)	To 1000 mL volume	n/a

INSTRUCTIONS FOR USE
The perfusate should be cooled to approximately 2–8°C (36–46°F) prior to use and should be used in a perfusion machine that is capable of maintaining temperature within the above specified range.

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 bag decanter into the Delivery Port with a twisting motion.
6. After pre-cooling the kidney by vascular flush using KPS-1, Kidney Perfusion Solution or another suitable cooled solution (SPS-1®, Ringer's, or saline), the kidney can be placed on a suitable perfusion apparatus and machine perfused according to the manufacturer's (or perfusion center's) protocol.

NOTE: For use with LifePort Kidney Transporter system, the recommended perfusate volume is 1000 mL for one human kidney.

CONSULT INSTRUCTIONS FOR USE: Follow the procedure in LifePort Kidney Transporter Operator's Manual for use with LifePort Kidney Transporter system.

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 can be used for a mean perfusion time of 29 ± 8 hours (Barber et al. *Transpl. Proc*. 1991). 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
No adverse reactions thought to be attributable to the perfusion solution have been observed when the solution is used as described.

KPS-1, Kidney Perfusion Solution includes constituent (Hydroxyethyl starch [HES]), which has caused hypersensitivity reactions in some patients. Physicians should be alert to treat possible reactions.

WARNINGS AND PRECAUTIONS

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

CAUTION: KPS-1, Kidney Perfusion Solution should be stored indoors in a dry location out of direct sunlight.

WARNING: Do not use if frozen, cloudy, or exposed to extreme heat.

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.

WARNING: Not intended for direct injection or intravenous infusion.

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.

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.

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), +55.11.98638.0086 (Brazil), or +33.967.23.0016 (France).

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EXPLANATION OF SYMBOLS

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

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