

KPS-1[®]

Kidney Perfusion Solution

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 approximate calculated osmolarity of 300 mOsM, a sodium concentration of 100 mEq/L, a potassium concentration of 25 mEq/L, and a pH of approximately 7.4 at room temperature. Based on the sodium/potassium ratio, the composition is thus consistent with that of an extracellular solution.

The perfusate should be cooled to approximately 5°C (2°C to 8°C) prior to use and should be used in a perfusion machine that is capable of maintaining temperature within the above specified range.

SUGGESTED VOLUME

The recommended perfusate volume is 1000 mL for one human kidney.

STORAGE

KPS-1 may be stored at room temperature and cooled before use. **Do not freeze or expose to excessive heat.**

PREPARATION

Remove clear overwrap prior to use. Carefully open the clear pouch being careful not to damage or tear the interior perfusate bag. If the interior perfusate bag is damaged during opening process, discard solution.

Inspect perfusate to ensure there is no particulate matter, precipitates, or contamination in the perfusate. If the perfusate is clear and no particulate is observed, the perfusate is safe to use.

NOTE: If the perfusate contains any particulate, contact Organ Recovery Systems to make arrangements to return perfusate to manufacturer.

After pre-cooling the kidney by vascular flushout using KPS-1 Kidney Perfusion Solution or other suitable cooled solutions (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.

contraindications

There are no known contraindications when used as directed

PRECAUTIONS

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

ADVERSE REACTIONS

No adverse reactions thought to be attributable to the perfusion solution have been observed when the solution is used as described.

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Instructions for Use

KPS-1[®] Kidney Perfusion Solution
(Having the same composition as University of Wisconsin Machine Perfusion Solution)*



European Authorized Representative

Ergo Europe

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 The Netherlands



Sterile Medical Devices
 Using Aseptic Technique
 (Aseptic Fill)

Expiration Date: YYYY/mm

WARNINGS

NOT FOR DIRECT INTRAVENOUS INFUSION

SOLUTION COMPOSITION

Constituents	Amount/1000 mL	Concentration, mM
Calcium chloride (dehydrate)	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

CAUTION

Federal and international law restricts this sale of this device to or on the order of a physician or licensed practitioner.

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