Belzer MPS® - 1000mL
(UW Machine Perfusion Solution)

Indications for Use:

Belzer MPS® (UW Machine Perfusion Solution) is intended for the in-vitro flushing and continuous hypothermic machine perfusion preservation of explanted kidneys.

Suggested Volume:

Bridge to Life Ltd. recommends a volume of 1000 mL of Belzer MPS® perfusate (one bag) for two (2) human kidneys.

Device Description:

Belzer MPS® is a clear to straw-colored solution for the in-vitro flushing and temporary continuous perfusion preservation of explanted kidneys. This solution is consistent with an extracellular solution, based on its sodium/potassium ratio. This solution has a calculated potassium concentration of 25 mEq/L, a sodium concentration of 100 mEq/L, an osmolarity of 300 mOsm, and a pH of approximately 7.4 at 20°C.

Storage Conditions:

Belzer MPS® solution should be stored between 2°- 25°C (36°- 77°F). While 5°C is the ideal temperature for actual perfusion of Belzer MPS®, a range of 4°- 8°C is acceptable. Do not freeze or expose to excessive heat.

Preparation and Administration:

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 Bridge to Life Ltd. to make arrangements to return.

Pre-cool the kidney by vascular flush-out using Belzer MPS® or other cooled solutions (2°-8°C) (Belzer UW® Cold Storage Solution, Ringers, or saline). The kidney can then be placed into a perfusion apparatus that is capable of maintaining temperature within the range of 2°-8°C. The kidney should be perfused following the manufacturer's or perfusion center's protocol. Belzer MPS® is suitable for a mean perfusion time of 29 hours ±8 hours.[1] Belzer MPS® should be flushed from the donor organ at the time of implantation.

For further information regarding clinical experience with organ preservation solutions, please contact the company for a bibliography of organ preservation articles.

Additives:

Possible additives, recommended by the University of Wisconsin include: Penicillin (150,000 units), Regular Insulin (40 units) and Dexamethasone (8 mg). The use of these additives is not required but rather is at the discretion of the Organ Procurement or Transplant professional.

Precautions:

Belzer MPS® is made with Hydroxyethyl Starch, which has been the cause of hypersensitivity reactions in patients. Also, if applicable, penicillin, insulin and dexamethasone have caused hypersensitivity reactions in patients. Physicians should be prepared to respond to possible reactions.

Warning:

This product is NOT intended for direct injection or I.V. use.

Solution Composition:

CONSTITUENT	AMOUNT/1000 ML	CONCENTRATION (mmol/L)
Adenine (free base)	0.68 g	5
Calcium Chloride (dihydrate)	0.068 g	0.5
Dextrose (+)	1.80 g	10
Glutathione (reduced)	0.92 g	3
HEPES (free acid)	2.38 g	10
Hydroxyethyl Starch	50.0 g	N/A
Magnesium Gluconate (anhydrous)	1.13 g	5
Mannitol	5.4 g	30
Potassium Phosphate (monobasic)	3.4 g	25
Ribose, D(-)	0.75 g	5
Sodium Gluconate	17.45 g	80
Sodium Hydroxide	0.70 g	N/A
Sterile Water for Injection	To 1000 mL Volume	N/A

Adverse Reactions:

When Belzer MPS® solution is used as described, no adverse reactions attributed to the solution have been observed.

Caution: Federal and certain international laws restrict the sale of Belzer MPS® to the order of a physician or a licensed practitioner.

Manufactured by:
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[1]WH Barber et. al.: Comparison of Simple Hypothermic Storage, Pulsatile Perfusion with Belzer's Gluconate-Albumin Solution, and Pulsatile Perfusion with UW Solution for Renal Allograft Preservation. Transplantation Proceedings, Vol. 23, No. 5 (October), 1991; pp 2394-2395