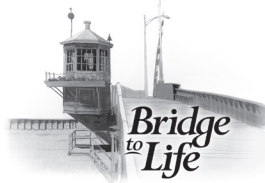


CE 2797

STERILE A

Sterile Medical Device
Using Aseptic Technique
(Aseptic Fill)



PHT

DEHP

RM/N 4088
Rev. 070820

Instructions for Use

Belzer MPS®

Organ Preservation Solution (UW Machine Perfusion Solution)



Single Use Only. Do NOT Reuse!!

INDICATIONS FOR USE

Belzer MPS® Organ Preservation Solution is intended for the *in-vitro* flushing and continuous hypothermic machine perfusion preservation of explanted kidneys.

SUGGESTED VOLUME

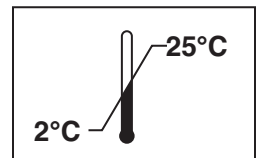
Bridge to Life Ltd. recommends a volume of 1000 mL of Belzer MPS® perfusate (one bag) for two (2) human kidneys.

DEVICE DESCRIPTION

Belzer MPS® Organ Preservation Solution 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 mosmol/kg, 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

Remove overwrap prior to use. 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) (UW Cold Storage Solution, Ringer's, 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 manufacturers or perfusionists protocol. Belzer MPS® is suitable for a mean perfusion time of 29 hours ±8 hours¹. 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 Bridge to Life Ltd. include: Penicillin (150,000 units), Regular Insulin (40 units) and Dexamethasone (8 mg).

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

Not intended for systemic administration by direct injection or intravenous infusion.

WARNING

Not for *in situ* flushing of organs in living donors or patients.

WARNING

Do not re-use. Re-use of transplant solution may cause infection or serological cross contamination.



Single Use Only. Do NOT Reuse!! Discard Any Unused Portion.

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	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 (USA) law restricts this device to sale by or on the order of a physician..

¹WH 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.



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