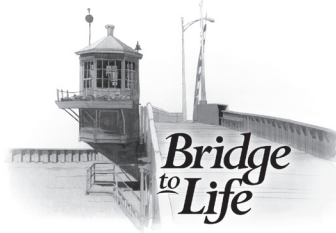


CE 0086

STERILE A

Sterile Medical Device
Using Aseptic Technique
(Aseptic Fill)



DEHP

RM/N 4097
Rev. 041618

Instruction for Use Belzer UW® Cold Storage Solution (University of Wisconsin)



Single Use Only. Do NOT Reuse!!

DIRECTIONS FOR PREPARATION AND USE

DESCRIPTION

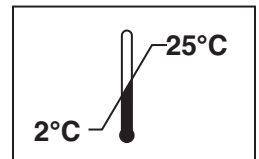
Belzer UW® Cold Storage Solution composition is:

	g/L	mmol/L		g/L	mmol/L
Pentafraction	50	N/A	Allopurinol	0.136	1
Lactobionic Acid (as Lactone)	35.83	105	Total Glutathione	0.922	3
Potassium Phosphate monobasic	3.4	25	Potassium Hydroxide	5.61	100
Magnesium Sulfate heptahydrate	1.23	5	Sodium Hydroxide/Hydrochloric Acid	Adjust to pH 7.4	N/A
Raffinose pentahydrate	17.83	30	Water for Injection	q.s.	N/A
Adenosine	1.34	5			

Belzer UW® Cold Storage Solution 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 mosmol/kg, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of approximately 7.4 at 20°C.

HOW SUPPLIED – STORAGE CONDITIONS

Belzer UW® Cold Storage Solution is supplied in one liter bags, shelf carton of 10, in two liter bags, shelf carton of 5, and in one-half (0.5L) liter bags, shelf carton of 6. Store Belzer UW® Cold Storage Solution indoors at temperatures controlled between 2 ° and 25°C (36° and 77°F). Avoid excessive heat. Do not freeze the solution, and do not use if frozen. Do not use if discolored or if obvious particulate matter, precipitates, or contamination are evident in the solution.



ACTIONS

Belzer UW® Cold Storage Solution 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. Belzer UW® Cold Storage Solution is to be used for cold storage of the organ and is not acceptable for continuous machine perfusion. Administration of Belzer UW® Cold Storage Solution, at the recommended temperature, will effectively cool the organ and lower its metabolic requirements.

INTENDED USE

Belzer UW® Cold Storage Solution 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

Hypersensitivity to adenosine, allopurinol, or any component of Belzer UW® Cold Storage Solution or suggested additives.

WARNINGS

NOT INTENDED FOR SYSTEMIC ADMINISTRATION BY DIRECT INJECTION OR INTRAVENOUS INFUSION.

NOT FOR *IN SITU* FLUSHING OF ORGANS IN LIVING DONORS OR PATIENTS.

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.

PRECAUTIONS

The donor organ must be flushed free of the Belzer UW® Cold Storage Solution 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 during donor organ retrieval to avoid cardiac arrest.

Belzer UW® Cold Storage Solution includes components (allopurinol and pentafraction) which individually have caused hypersensitivity reaction in patients. Additionally, the additives recommended for use with Belzer UW® Cold Storage Solution (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 fresh Belzer UW® Cold Storage Solution was used for repeat flushing of the organ within three (3) hours prior to transplant, or when Belzer UW® Cold Storage Solution was not thoroughly flushed from the organ prior to transplant.

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.

The following can be added aseptically to each liter of Belzer UW® Cold Storage Solution immediately before use:

1. Penicillin G, 200,000 units
2. Regular Insulin, 40 units
3. Dexamethasone, 16 mg

Glutathione, one of the components of Belzer UW® Cold Storage Solution, oxidizes during storage. If desired, an additional 0.922 g/L (3 mmole/L) of glutathione may be added if Transplant Center policy or Surgical Personnel requirements call for its use. (Boudjema et al, Transpl. Proc. 23[5]1991; Merion et al, Transpl. Proc. 23[4]1991).

Remove protective cap from the bag outlet port designated delivery set port. Insert the spike from the administration set into the bag port with a twisting motion. Open clamp on administration set. Hold the administration set vertically above the solution bag, then squeeze the solution bag into the administration set. Close the clamp.

Prior to connection to the organ, the solution container should be suspended from a sufficient height to allow for a steady stream of solution and to produce flow rates of at least 30 mL/min during flushing. Open the clamp to begin flushing. Flushing should be continued until the organ is uniformly pale and the effluent is relatively clear.

SUGGESTED MINIMUM VOLUMES

<i>In situ</i> aortic flush:	Adults, 2-4 L Infants, 50 mL/kg
<i>Ex vivo</i> infusion:	liver (via portal vein and biliary tree) Adults, 1200 mL Infants, 50 mL/kg
Pancreas or Kidney:	Adults, 300-500 mL Infants, 150-250 mL

Additional solution should be dispensed into the container holding the organ. Seal the container aseptically. The organ storage container should be maintained within a well-insulated transport container. Ice should be used to surround the organ storage container, but should not be used within the container, where the ice could come into direct contact with the organ. Donor organs must be flushed free of Belzer UW® Cold Storage Solution prior to anastomosis (Refer to PRECAUTIONS Section.). In order to minimize residues of the solution in the liver, just prior to anastomosis, flush one liter of Lactated Ringer's through the hepatic portal vein.

ISCHEMIA TIMES

The recommended following times for each organ are:

<u>Cold Ischemia Times</u>		<u>Warm Ischemia Times</u>	
Liver	not longer than 17 hours	Liver	not longer than 2.5 hours
Kidney	not longer than 23 hours	Kidney	not longer than 2.5 hours
Pancreas	not longer than 21 hours	Pancreas	not longer than 2.5 hours

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



Manufactured By:
Preservation Solutions, Inc.
1099 Proctor Drive
Elkhorn, WI 53121 USA
+1.262.723.6715 Telephone
+1.262.723.4013 Fax

Distributor:
Bridge to Life (Europe) Ltd
a subsidiary of Bridge to Life Ltd.
LU 311 The Light Bulb
1 Filament Walk
London SW18 4GQ
United Kingdom
+44 (0) 20 3411 8326 Telephone



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands