



Belzer UW® Cold Storage Solution

(UW Solution)

Directions for Preparation and Use

Not for Direct Injection or Intravenous Infusion

Description:

Belzer UW® Cold Storage Solution (UW Solution) composition is:

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

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 mOsm, a sodium concentration of 29 mEq/L, a potassium concentration of 125 mEq/L, and a pH of approximately 7.4 at 20°C.

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:

There are no known contraindications when used as directed.

Warnings:

NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION.

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 the organ has been reflushed with fresh solution within a short period (1 to 3 hours) prior to release of vascular anastomosis clamps in the recipient, or when inadequate flush-out of the solution has occurred.

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 **per liter**
2. Regular Insulin, 40 units **per liter**
3. Dexamethasone, 16 mg **per liter**

The use of these additives is not required but rather is at the discretion of the Organ Procurement or Transplant professional.

How Supplied:

500 mL in 500 mL bags, shelf carton of 6; 1000 mL in 1-liter bags, shelf carton of 10; 2000 mL in 2-liter bags, shelf carton of 5. Store Belzer UW[®] Cold Storage Solution indoors at temperatures controlled between 2° and 25°C (36° and 77°F) until use. 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.

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

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