

SOLUTION COMPOSITION

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	qs

CSS 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.

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

WARNING

NOT INTENDED FOR DIRECT INJECTION OR INTRAVENOUS INFUSION.

PRECAUTIONS

The donor organ must be flushed free of the CSS 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.

CSS includes components (allopurinol and pentafraction) which individually have caused hypersensitivity reaction in patients. Additionally, the additives recommended for use with CSS (penicillin, insulin, and dexamethasone) have individually been associated with hypersensitivity reactions in patients. Physicians should consult individual drug labelling and be alert to treat possible reactions.

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



Waters Medical Systems

2112 15th St. NW | Rochester, MN 55901 | USA
Tel. +1 507 288 7777 | Fax +1 507 252 3700
www.groupe-igl.com | welcome@groupe-igl.com

Please contact us for a complete list of references and authorizations.