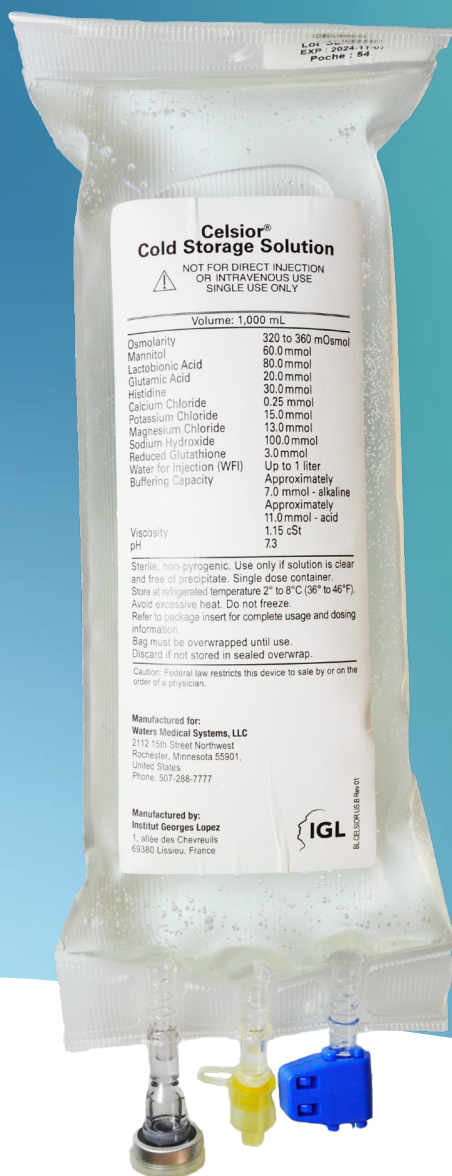




NEW CHANCES  
MATTER



# CELSIOR®

Flushing and Cold Storage Solution for Heart  
Preservation

## COMPOSITION

Celsior® is a clear to slightly yellow, sterile, non-pyrogenic solution for hypothermic flushing and storage of hearts. The solution is slightly acidic (approximate pH 7.3 at 20°C), slightly hypertonic (approximate calculated osmolarity 320-360 mOsmol/L) with low viscosity (1.15 cSt), and has a high buffering capacity (acidic approximately 11 mmol, alkaline approximately 7 mmol).

INGREDIENT	AMOUNT (G/L)	AMOUNT (MMOL)
Mannitol	10.930g/L	60 mmol
Lactobionic Acid	28.664g/L	80 mmol
Glutamic Acid	2.942g/L	20 mmol
Histidine	4.650g/L	30 mmol
Calcium Chloride	0.037g/L	0.25 mmol
Potassium Chloride	1.118g/L	15 mmol
Magnesium Chloride	2.642g/L	13 mmol
Sodium Hydroxide	4.000g/L	100 mmol
Reduced Glutathione	0.921g/L	3 mmol
Water for Injection	Upto 1liter	Up to 1 liter

## MECHANISM OF ACTION

Celsior® is intended for flushing and cold storage of hearts at the time of their removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient. Administration of Celsior® cools the organ, and therefor reduces its metabolic requirements and associated energy consumption. Celsior® is specially formulated for optimal preservation of heart organs.

<b>ANTIOXIDANTS</b>	Glutathione (in a stable reduced form)
	Histidine
	Lactobionic acid
	Mannitol

Celsior® guarantees the antioxidant action, with permanently reduced glutathione, histidine, lactobionate and mannitol.

<b>IONIC COMPOSITION</b>	Sodium hydroxide
	Potassium chloride
	Calcium chloride
	Magnesium chloride

With a low potassium, low calcium and high magnesium content, Celsior® can be used for the heart organs, protecting against calcium overload.

## IMPERMEANTS AND MEMBRANE STABILIZERS

Lactobionic acid

Mannitol

Celsior®'s composition of impermeants helps to avoid the swelling of cells during cold ischaemic storage.

## BUFFER

Histidine

Celsior® contains histidine, which has an excellent capacity for hydrogen ion buffering<sup>1</sup> thereby protecting grafts from acidosis.

## HIGH-ENERGY SUBSTRATES

Glutamic acid

Celsior® contains substrates that help the production of energy in anaerobic conditions.

## CLINICAL BENEFITS

CELSIOR® IS ASSOCIATED WITH SUPERIOR OUTCOMES IN GRAFT FUNCTION VS HTK.

**Table 1.** Clinical cardiac outcomes following heart transplantation. Prospective, open-label study<sup>2</sup>

OUTCOME	CELSIOR® (n=16)	UW (n=17)	HTK (n=15)	P-VALUE
Spontaneous sinus rhythm	12(75,0%)	5(29.4%)	5(33,3%)	0,01
Cardiac output (L/min)	6,49±1,02	6.16±0,93	5,57±0,87	0,03

**Table 2.** Clinical outcomes following heart transplantation. Preliminary single-centre data from a prospective, randomised, multicentre study<sup>3</sup>

OUTCOME	CELSIOR® (n=24)	HTK (n=24)
Acute graft failure	1/24	2/24
Spontaneous sinus rhythm	19/24	9/24
Donor heart dysfunction	2/24	7/24
Adrenaline equivalent for weaning from extracorporeal circulation	0,054±0,17	0,085±0,066

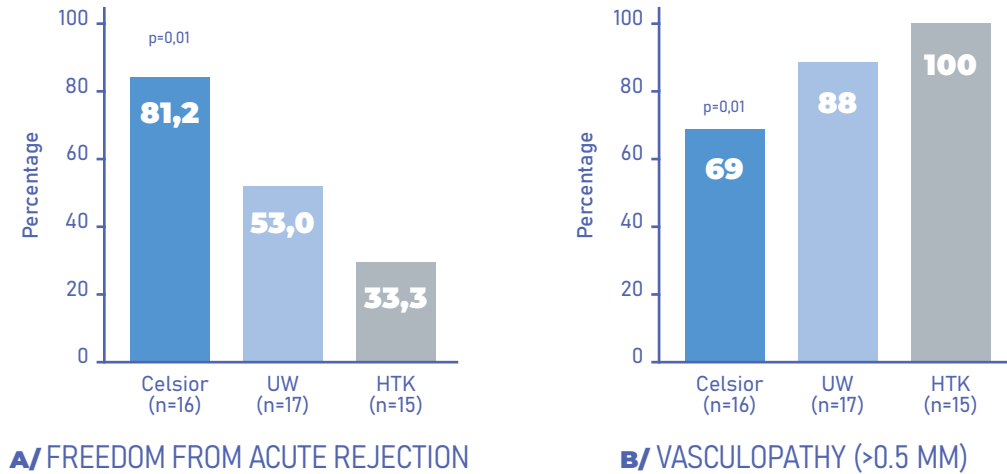
PERFUSION VOLUMES ARE LOW WITH CELSIOR®.

A volume of 1-2L of Celsior® solution is recommended for perfusion of an adult donor heart.

1. Menasche P, Termignon JL, Pradier F, et al. Experimental evaluation of Celsior®, a new heart preservation solution. Eur J Cardiothorac Surg 1994;8(4):207-13.
2. Garlicki M. May preservation solution affect the incidence of graft vasculopathy in transplanted heart? Ann Transplant 2003;8(1):19-24.
3. Wieselthaler GM, Chevchik O, Konetschny R, et al. Improved graft function using a new myocardial preservation solution: Celsior. Preliminary data from a randomized prospective study. Transplant Proc 1999;31(5):2067-8.

CELSIOR® IS ASSOCIATED WITH A REDUCED INCIDENCE OF GRAFT REJECTION.

**FIGURE A AND B.** Graft rejection and vasculopathy rates following heart transplantation. Prospective, open-label study comparing Celsior, HTK and UW showed significantly reduced acute rejection and vasculopathy for Celsior (p=0.01 for both outcomes)<sup>2</sup>.



### **BENEFITS OF CELSIOR® :**

- Specially formulated for Heart Preservation
- Superior outcomes compared to HTK<sup>1,2</sup>
- Easy to transport and stock due to low required perfusion volumes
- Low viscosity leading to lower perfusion pressure and safety for smaller blood vessels
- Ready to use: no additives required, no filtering required
- Available in 1000ml bag equipped with easy perfusion spike port and additive port
- EVA bag, free from PVC, latex and phthalates, to guaranty excellent biocompatibility properties
- Oxygen absorber in packaging to reduce degradation of the solution components
- EVA bag overwrapped with an aluminium-protected bag to protect from light
- Manufactured by ISO 13485 certified company



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