Paragonix SherpaPak™

Cardiac Transport System

Clinical Update 1

Cooler Method: <2°C Risks Cold Injury and Preservation Solution Crystallization in Donor Hearts

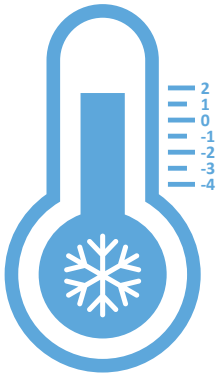
Perception: The Colder the Better

Reality:

- Donor hearts when transported in preservation solutions inside the conventional cooler method risk cold injury at <2°C in less than 30 minutes due to the cooler method having an uncontrolled temperature range.[1-5]
    - o When a preservation solution reaches <2°C, "histidine may flocculate and crystalize…[which] may cause serious damage to the organs."[6]
    - o At subzero temperatures, "macroscopically visible and indissoluble particles have been observed" (Fig. 1).[7]
- The temperature range of three commercially available preservation solutions indicate they should be at 2-8°C or 2-6°C, according to their approved labeling.[8-10]
    - o The labeling of two preservation solutions also states "do not freeze"[9,10] and one states "do not use if frozen."[10]

Solution: **Paragonix** SherpaPak™ CTS

- The only FDA cleared and CE marked transport device for heart transplantation provides a controlled temperature outside the range of cold injury (<2°C) for 40+ hours.[5,*]
- The device maintains the optimal temperature range for the preservation solution and organ for transplant.[5]
- The device provides real-time temperature monitoring for temperature verification and reporting via Bluetooth® to mobile devices for data analysis.



<2°C Risks Cold Injury

"Adequate storage temperatures of both grafts and perfusion solutions […] seem of major importance in avoiding potential graft injuries."[7]

- Dr. Tullius et al.

Department of Surgery, Charite´ Virchow Clinic
Department of Clinical Chemistry, Charite´
(Berlin, Germany)

Fig. 1: Indissoluble crystal particles in organ stored in preservation solution at subzero °C

Indissoluble crystal particles (white specs below) were observed in an organ stored in preservation solution at subzero temperatures (d/polarization microscopy at 125x)[7]

1. Michel et al., Heart, Lung, and Vessels 2015; 7(3):246-255. **2.** Ingemansson et al., Ann Thorac Surg. 1996; 61; 1413-7. **3.** Mankad et al., J Thorac Cardiovasc Surg 1992; 104: 1618-1624. **4.** Keon et al. Ann Thorac Surg 1988; 46:337-341. **5.** Paragonix, Data on file. **6.** Letter on file from manufacturer of Custodial HTK, Essential Pharmaceuticals, from Deputy Head of Quality Assurance, April 17, 2019. **7.** Tullius et al., Am J Transpl 2002; 2: 627–630. Note: The organ in this study is a kidney. **8.** Custodial HTK Solution Prescribing Information. Downloaded on 03/19/2019 at https://www.custodiol.com/prescribing-info/ **9.** Celsior Package Leaflet. DCP4 REV03, 8/31/2018. **10.** Belzer UW® Cold Storage Solution Instructions for Use. RM/N 4107 Rev. 060816. Downloaded on 03/19/2019 at https://bridgetolife.com/wp-content/uploads/2015/11/belzer-uw-cold-storage-solution-multi-size-instructions-2.pdf

*Indications for Use: The Paragonix SherpaPak™ Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient using cold storage solutions indicated for use with the heart. The intended organ storage time for the Paragonix SherpaPak™ Cardiac Transport System is up to 4 hours. Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.

FDA CLEARED CE 2797

L-043 Rev A

US Orders: +1 781.428.4153
orders@paragonixtechnologies.com
EU Orders: eu-orders@paragonixtechnologies.com
www.ParagonixTechnologies.com

Paragonix Technologies, Inc.
639 Granite Street
Suite 408
Braintree, MA 02184
USA

Paragonix Technologies, Inc.
Lilienthalstrasse 8
85399 Hallbergmoos
Germany

PARAGONIX®
Advancing Organ Preservation