

Guiding Principles

PARAGONIX®



Advance
Organ
Preservation

Improve
Patient
Outcomes

Do No
Harm

Reduce
Healthcare
Costs

Paragonix SherpaPak[™] Cardiac Transport System

Product Overview



**Preventing
Cold Injury
in Transplants**

FDA CE
CLEARED 2797

Paragonix SherpaPak™ Cardiac Transport System

Summary



The ONLY commercially available FDA cleared and CE marked static medical device for donor heart transportation

- Use with any FDA-cleared preservation solution indicated for donor hearts



Maintains safe organ preservation temperature

- Controlled temperature across donor heart
- Storage temperature is validated for 40+ hours



Complete immersion of donor organ in preservation solution

- Donor heart is fully immersed and suspended for even cooling in preservation solution
- Two rigid sterile canisters plus Paragonix SherpaPak™ CTS insulated Shipper provide triple barrier protection of organs
- Meets or exceeds UNOS/AOPO Organ Packaging Guidelines



Monitor and record organ temperature

- Continuously measures and displays temperature during preservation and transport
- Temperature reporting via Bluetooth with mobile devices



Indications

- 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.

Product Highlights



Feature	Benefits
Paragonix SherpaPak™ Cardiac Transport System with CoolSafe™ Technology – 38 patents*	Consistent temperature range prevents cold injury
Temperature Probe	Continuous monitoring of temperature
Heart Connector – for most aortic diameters	Heart fully suspended and immersed for even cooling in preservation solution
Dual-Canister with Carrying Handle	Easy to carry, pressure-controlled, leak-proof and rigid to safeguard the heart
Paragonix SherpaCool™ Ribbons and Pouch	Consistent storage temperature range validated for 40+ hours
Shipper with Telescoping Handle and Wheels	A rigid protective barrier that is easy to move and compact
Display and Bluetooth® Data Transmission	Real-time monitoring (Fig. 1) and data reporting via Bluetooth® with mobile devices (Fig. 2)



Fig. 1: Digital display of temperature.

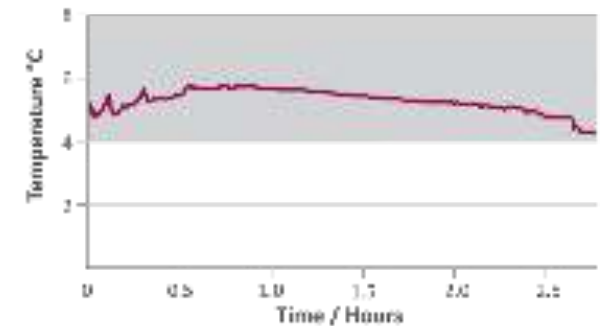


Fig. 2: Actual data record example of transport time and temperature.

Paragonix SherpaPak™ CTS vs. Cooler Method Paragonix SherpaPak™ CTS provides the following advantages to optimize the donor gift in life-preserving transplants:	Paragonix SherpaPak™ Cardiac Transport System	Cooler Method
Follows clinically practiced cold storage methods	✓	✓
CoolSafe™ technology provides consistent temperature and prevents cold injury for 40+ hours*	✓	✗
Heart fully suspended and immersed in preservation solution for even cooling	✓	✗
Pressure-controlled, leak-proof and rigid canisters safeguard the kidney	✓	✗
Real-time monitoring and data reporting	✓	✗
FDA cleared and CE marked device	✓	✗

*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.

Clinical Feedback

Paragonix SherpaPak™ CTS

“I do think the [Paragonix] SherpaPak™ CTS has the potential to become the standard of care in heart transplantation.”¹

Dr. David D’Alessandro et al. Massachusetts General Hospital (Boston, MA)

“I’ve never seen a heart wake like this in my 15 years of doing heart transplantation.”²

Dr. Jonathan Philpott, Cardiothoracic Surgeon, Sentara Hospital (Norfolk, VA)

Cooler Method

“[Uncontrolled temperatures are] a major issue and most people getting the hearts don’t understand this is a problem.”²

Dr. Jonathan Philpott, Cardiothoracic Surgeon, Sentara Hospital (Norfolk, VA)

“Current cold storage heart preservation technique is associated with wide fluctuation of organ temperature and may result in freeze injury.”³

Dr. David D’Alessandro et al. Massachusetts General Hospital (Boston, MA)

Cooler Method



Uneven cooling with risk of cold injury ($<2^{\circ}\text{C}$) due to uncontrolled temperatures^{1,2}



Unknown temperature

Unvalidated storage containers with risk of leaks



No data reports of temperature during transport



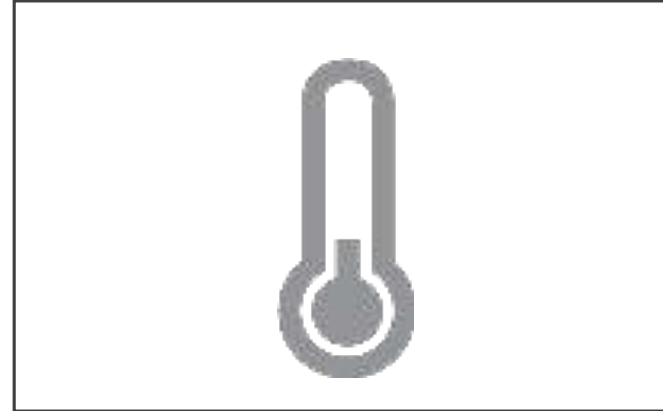
1. Data on file. 2. Michel et al., Journal of Heart, Lung, and Vessels. 2015; 7(3):246-255.

Paragonix SherpaPak™ Cardiac Transport System



Evenly cooled and fully immersed in
preservation solution

Pressure-controlled, leak-proof and rigid
canisters safeguard the kidney



Controlled temperature prevents
cold injury for 40+ hours

Real-time monitoring and data reporting



Ordering and Support

	US	EU
Orders	+1 781.428.4153	orders@paragonixtechnologies.com
Support	+1 781.428.4828 (24 hours/7 days a week)	eu-support@paragonixtechnologies.com

Learn More at: www.ParagonixTechnologies.com



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Product Information

Paragonix SherpaPak™ Cardiac Transport System (CTS) is designed to advance organ preservation and improve outcomes by preventing cold injury to the donor organ in heart transplants through proprietary CoolSafe™ technology that is capable of maintaining a consistent temperature range.

Product Name	Product Code
Paragonix SherpaPak™ Cardiac Transport System	SHRP-1001-000

SHIPPER	CANISTERS	SherpaCool™ POUCH & RIBBONS
Rigid Insulated Barrier with Temperature Display	Two nesting sterile Canisters with lids and four Heart Connector sizes	Proprietary cooling technology
