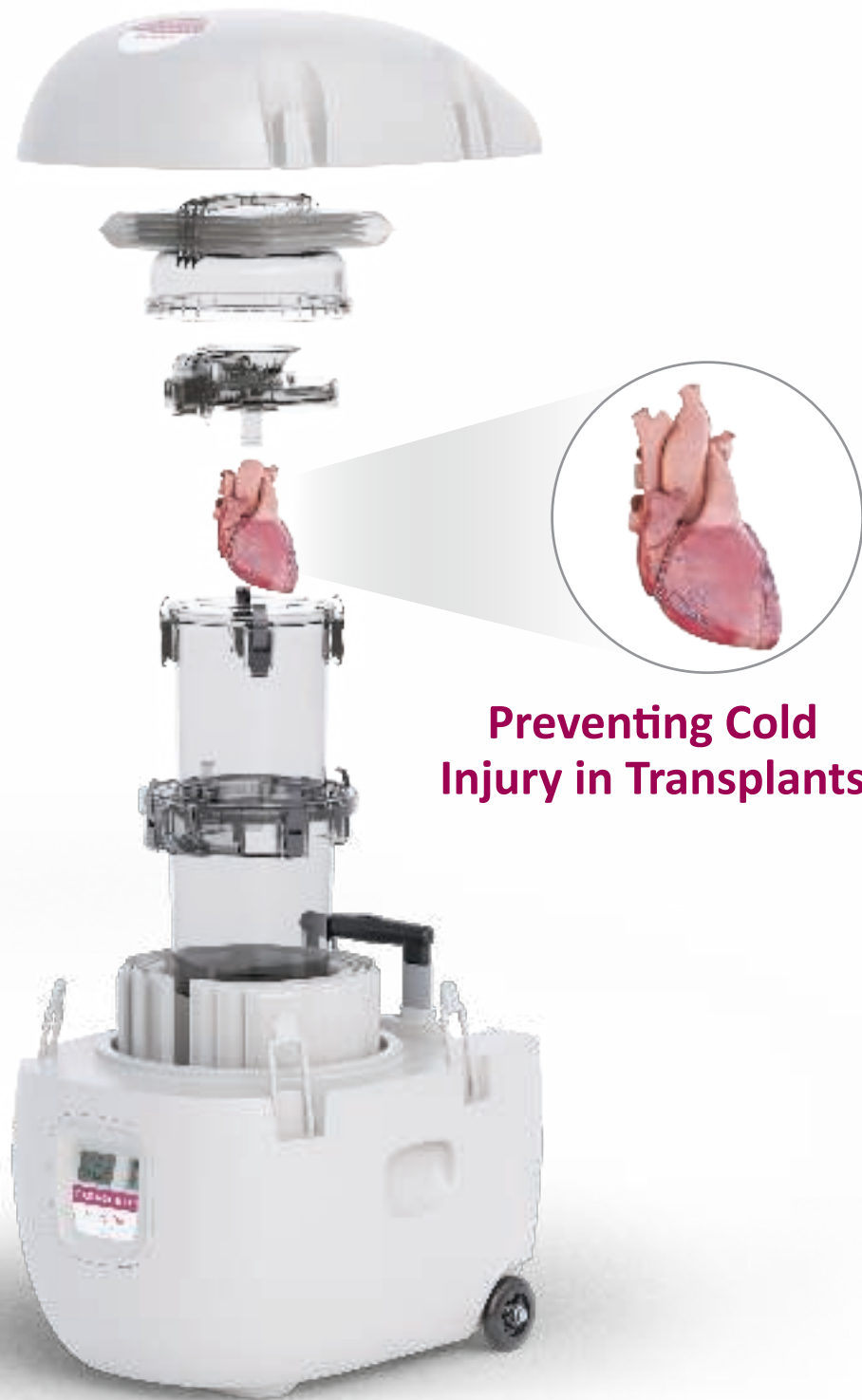


PARAGONIX[®]



**Preventing Cold
Injury in Transplants**

Paragonix SherpaPak[™]

Cardiac Transport System

Cardiac Transport System


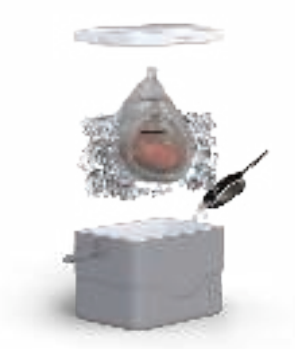
Advancing Organ Preservation

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.

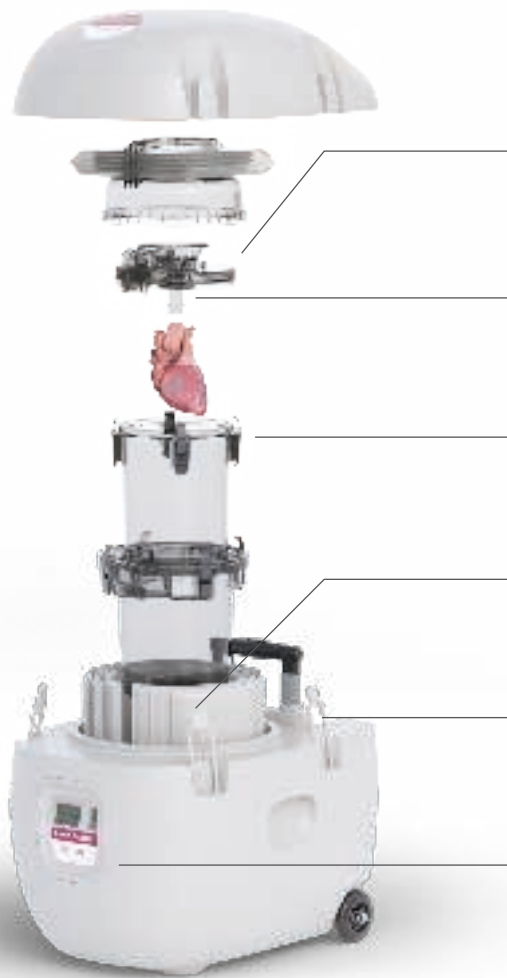
Paragonix SherpaPak™ CTS vs. Cooler Method

Paragonix SherpaPak™ CTS provides the following advantages to optimize the donor gift in life-preserving transplants:



	Paragonix SherpaPak™ CTS	Cooler Method
		
Follows clinically practiced cold storage methods	✓	✓
CoolSafe™ technology provides a consistent temperature range and prevents cold injury	✓	✗
Heart fully suspended and immersed in preservation solution for even cooling	✓	✗
Pressure-controlled, leak-proof and rigid canisters safeguard the heart	✓	✗
Real-time monitoring and data reporting	✓	✗
FDA cleared and CE marked device	✓	✗

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.

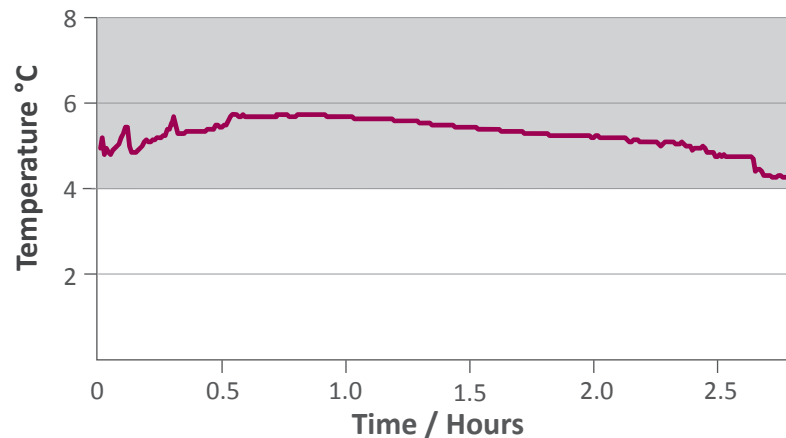
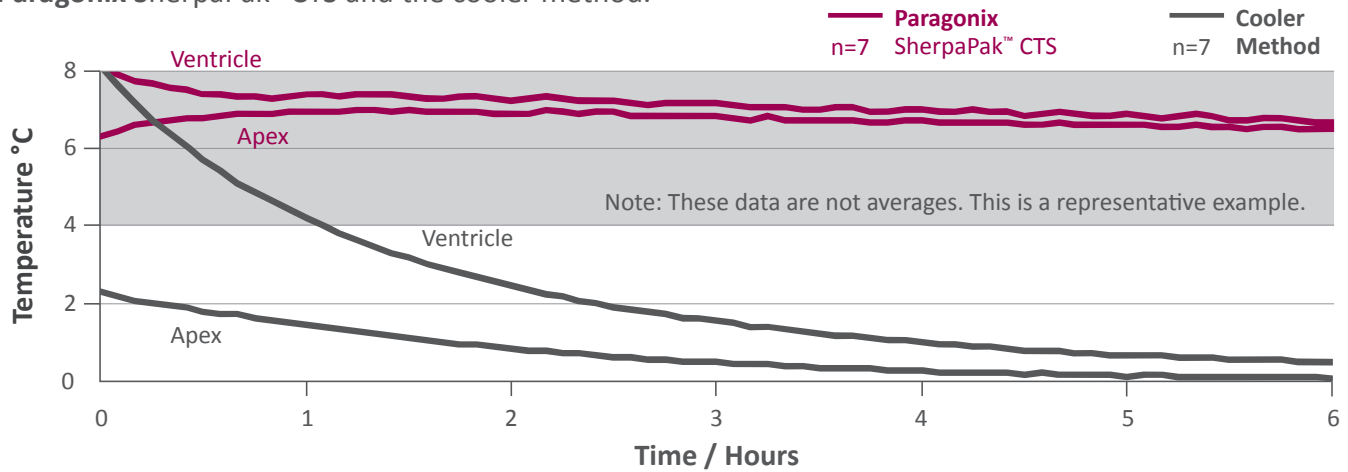


Fig. 2: Actual data report example of transport time and temperature.

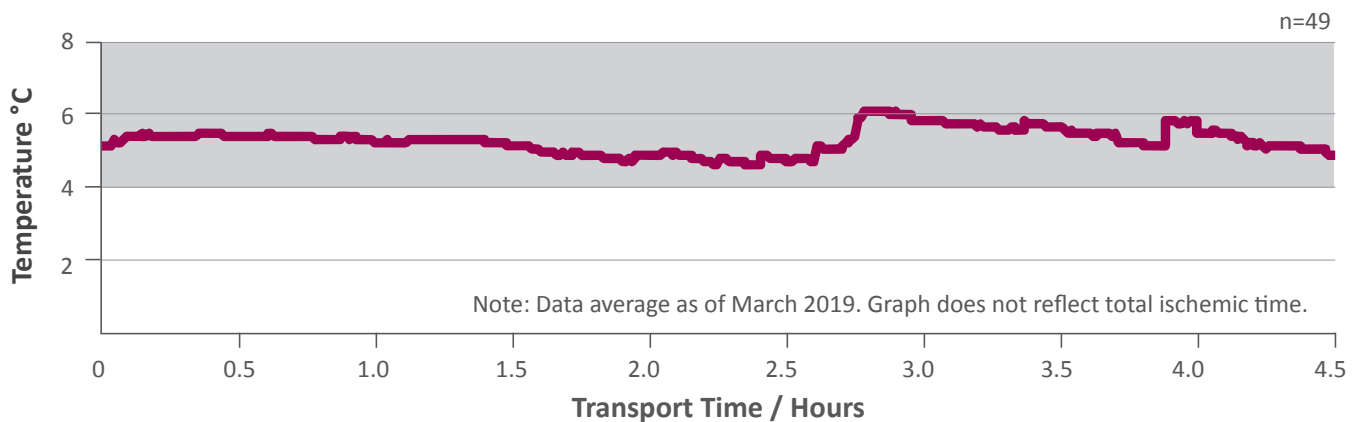
Validation Data: Paragonix SherpaPak™ CTS vs. Cooler Method¹

Side-by-side comparison: Ventricular and apical temperatures measured with probes placed inside a pig heart in Paragonix SherpaPak™ CTS and the cooler method.



- Paragonix SherpaPak™ CTS provides a consistent temperature outside the range for cold injury (<2°C).²
- In contrast, the cooler method allows a wide temperature gradient within the heart and reaches the temperature range for cold injury (<2°C).²

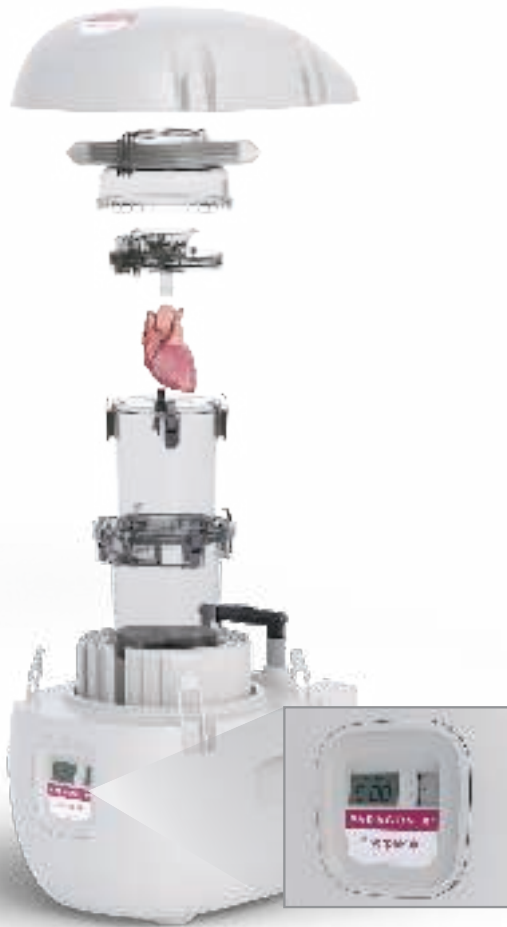
Human Data: Paragonix SherpaPak™ CTS¹



US and EU Clinical Experience			
Paragonix SherpaPak CTS™ Internal Temperature (°C)	Mean: 5.2	Min (Mean): 4.1	Max (Mean): 6.0
Paragonix SherpaPak CTS™ Transport Time (minutes)	Mean: 134	Min: 7	Max: 279*
Total Ischemic Time (minutes)**	Mean: 236	Min: 87	Max: 420
% of Transports where >4 Hours of Total Ischemic Time**	43%		
# Adverse Events / # Device Failures	0 / 0		

- Paragonix SherpaPak™ CTS provides a consistent temperature outside the range for cold injury (<2°C).²

Paragonix SherpaPak™ Cardiac Transport System



- Evenly cooled with a consistent and validated preservation temperature range
- Real-time monitoring to confirm temperature and reporting for data analysis

Clinical Feedback:

"[With Paragonix SherpaPak™ CTS], the transport went very well controlled. It was amazing to actually know the temperature of the heart during transport. Patient is doing great."

"I've never seen a heart wake like this in my 15 years of doing heart transplantation."

Cooler Method



- Unevenly cooled with a risk of cold injury ($<2^{\circ}\text{C}$) due to inconsistent temperatures^{1,2}
- Unknown temperature with no data reporting

Clinical Feedback:

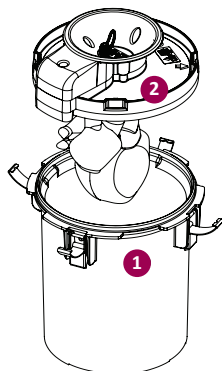
"Regulated temperature is important... It's a major issue and most people getting the hearts don't understand this is a problem."

"Crazy we don't know what the actual temperature of the donor heart is during transport!"

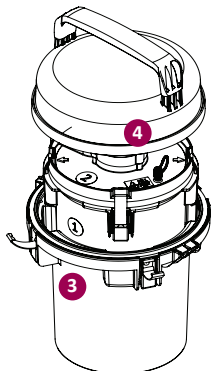
Cardiac Transport System

Quick Reference Steps: Organ Removal and Transit³

STERILE

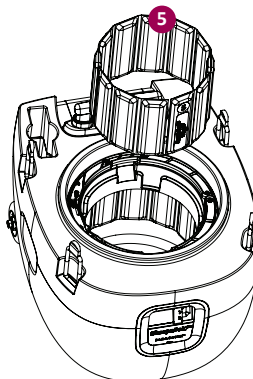


- 1** Organ Canister filled with solution
- 2** Heart anchored to lid, close lid, fill with solution and purge air using ports

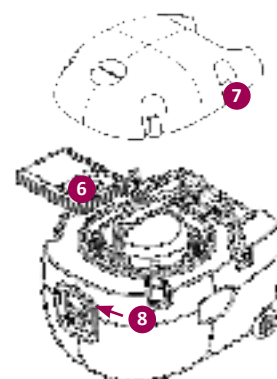


- 3** Shell base receives Organ Canister
- 4** Shell lid closed

NON-STERILE



- 5** SherpaCool™ Ribbons lining Shipper



- 6** SherpaCool™ Pouch under handle
- 7** Shipper lid closed
- 8** Data Logger button 1 pressed. Temperature and time logged.

Learn More at:



Paragonix® App

App Includes: Videos, Tutorials, Checklist, Quiz, Instructions for Use, Brochures, Data, and more.

Download at: Apple App Store or Google Play

www.ParagonixTechnologies.com

Ordering, Support and Product Information

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Support	+1 781.428.4828 (24 hours/7 days a week)	eu-support@paragonixtechnologies.com
	support@paragonixtechnologies.com	
Product Name		Product Code
Paragonix SherpaPak™ Cardiac Transport System		SHRP-1001-000

*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.



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1. Data on file. 2. Michel et al., Heart, Lung, and Vessels 2015; 7(3):246-255; 3. Please refer to Instructions for Use for full prescribing information.
*Patents issued and pending
**n=37

PARAGONIX®
Advancing Organ Preservation