

Paragonix SherpaPak™

# Cardiac Transport System

International Heart  
Summit, ISHLT 2019  
Clinical Highlights



**PARAGONIX®**  
Advancing Organ Preservation

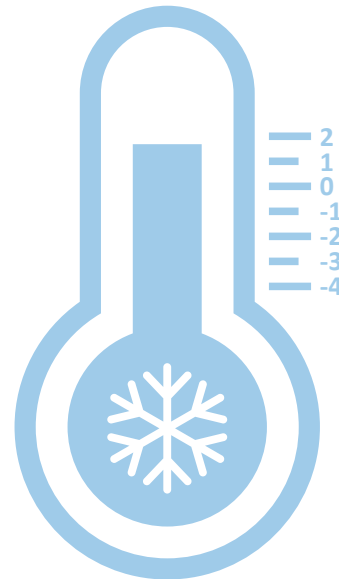
# Cardiac Transport System

## Cold Injury in Transplantation

### Perception: The Colder the Better

### Reality:

- “Most mammalian cells can withstand low temperatures for short periods of time when ice is not present.”<sup>1</sup>
- “Temperatures below 2°C significantly increase the risk of cold injury with some proteins denaturing below 0°C.”<sup>2-4</sup>
- “[It] is evident that the [diastolic function of the heart and elastance of those muscles] is irreversibly suppressed following exposure to temperatures of 1°C...”<sup>5,6</sup>



### Risks: <2°C

- <2°C: Cold injury<sup>2-4</sup>
- 1°C: Irreversible suppression of diastolic function<sup>5,6</sup>
- 0°C: Proteins denature<sup>2-4</sup>

*“With the ice box, sometimes we have hearts that are really cold with frostbite which is troublesome for us and is also associated with longer reperfusion times.”<sup>6</sup>*

**Dr. Andreas Zuckermann**, Cardiothoracic Surgeon, AKH (Vienna, Austria)

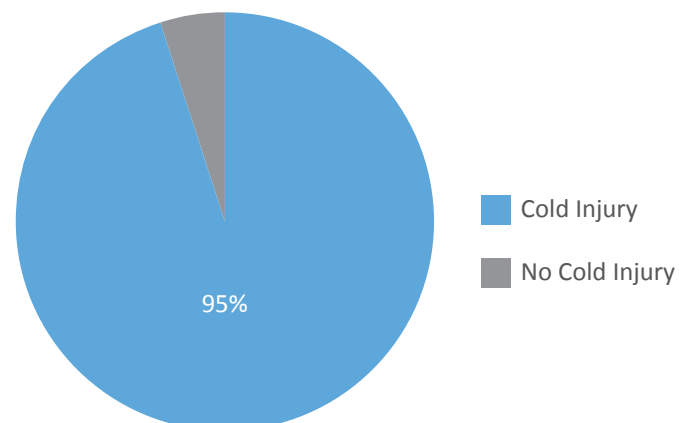
## Challenges with the Cooler Method

- In less than 30 minutes, the heart reaches <2°C and risks cold injury<sup>2-4,7</sup>
- Uncontrolled and uneven cooling<sup>1-7</sup>
- Unknown temperature with no data reporting

*“Heart transplantation has been around for over 50 years now....[and] it’s time to be a little more scientific about how we do this.”<sup>6</sup>*

**Dr. David D’Alessandro**, Cardiothoracic Surgeon, Massachusetts General Hospital (Boston, MA)

### Cooler Method: Estimated Incidence of Cold Injury for Donor Hearts



The survey results from an ISHLT Symposium indicate that 95% of cardiothoracic surgeons and cardiologists report cold injury with the cooler method which may be of concern.<sup>5</sup>

## Clinical Feedback: Paragonix SherpaPak™ CTS<sup>6</sup>

*"Definitely a game-changer. The hearts are different when they come back. They are soft, not frozen, not stiff."*

*"After you take the cross-clamp off, the first beat is different... it's like a hammer is being dropped which is radically different than what I was used to."*

*"We had this discussion about who do we use it on — just short or long runs? ... After seeing the results being so good, we immediately started using it for everybody."*

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

*"Paragonix SherpaPak™ CTS is an innovative alternative to improve the organ preservation. It is safe and handy, especially in prolonged ischemia."*

**Dr. Andrea Eixeres**, Cardiothoracic Surgeon, Hospital 12 de Octubre, (Madrid, Spain)

*"It's pretty easy to use after one afternoon of training. It's well built, stabile, and easy to transport."*

*"Compared to the ice box, these hearts felt colder, but really soft and tender."*

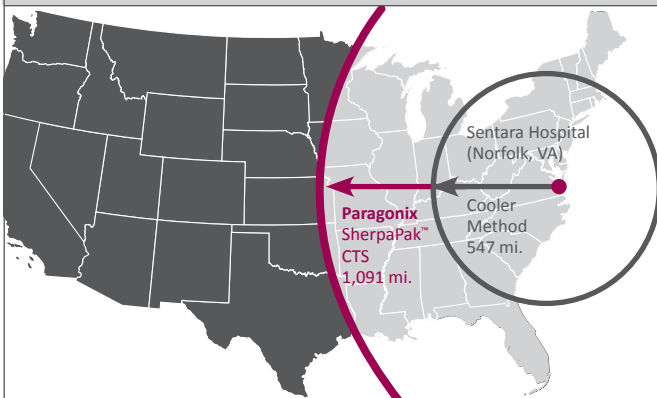
**Dr. Andreas Zuckermann**, Cardiothoracic Surgeon, AKH (Vienna, Austria)

*"For the heart connectors, you did a great job with providing different sizes even for younger donors."*

**Dr. Julia Dumfarth**, Cardiothoracic Surgeon, Medical University Innsbruck (Innsbruck, Austria)

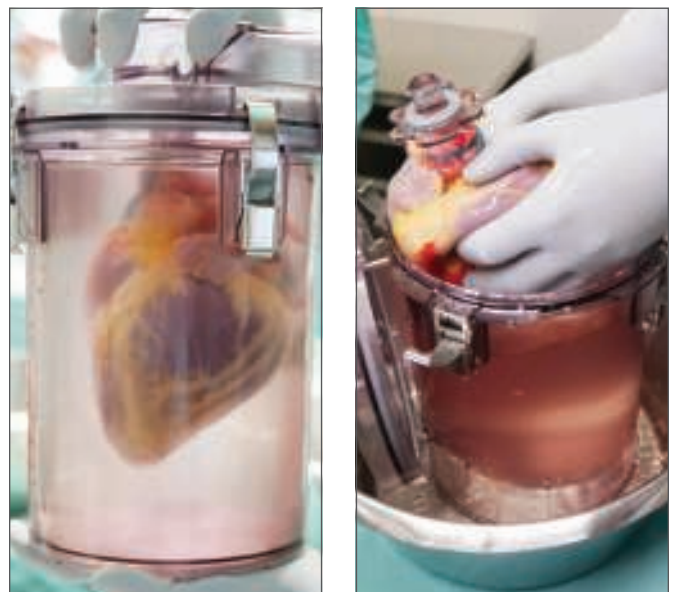
### Expanding Ischemic Time and Donor Opportunity with Paragonix SherpaPak™ CTS vs. Cooler Method<sup>6,8</sup>

Sentara Hospital transplant program was able to expand their opportunity for donor hearts by 55% (>67M potential donors, 10 additional US states) using **Paragonix SherpaPak™ CTS** that provides a controlled and consistent temperature for 40+ hours.\*



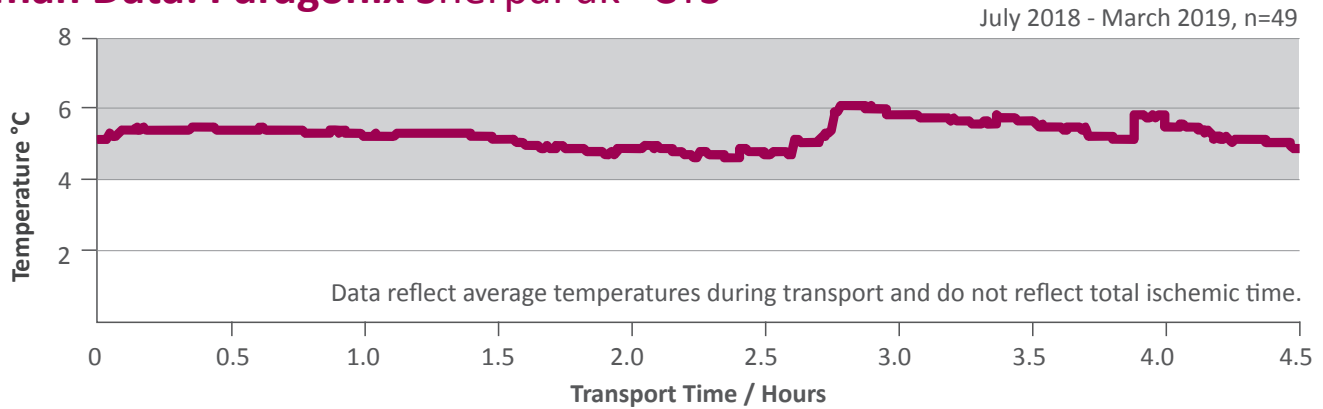
Inner Circle = maximum distance traveled with cooler method vs. Outer Circle = maximum distance traveled with **Paragonix SherpaPak™ CTS**.

### Paragonix SherpaPak™ CTS in Clinical Use<sup>6</sup>



Donor heart is fully suspended and immersed for even cooling in preservation solution (left image) and then removed (right image) from the **Paragonix SherpaPak™ CTS** dual-cannister assembly. (Photo: Medical Univ. Innsbruck)

## Human Data: Paragonix SherpaPak™ CTS<sup>7,9</sup>

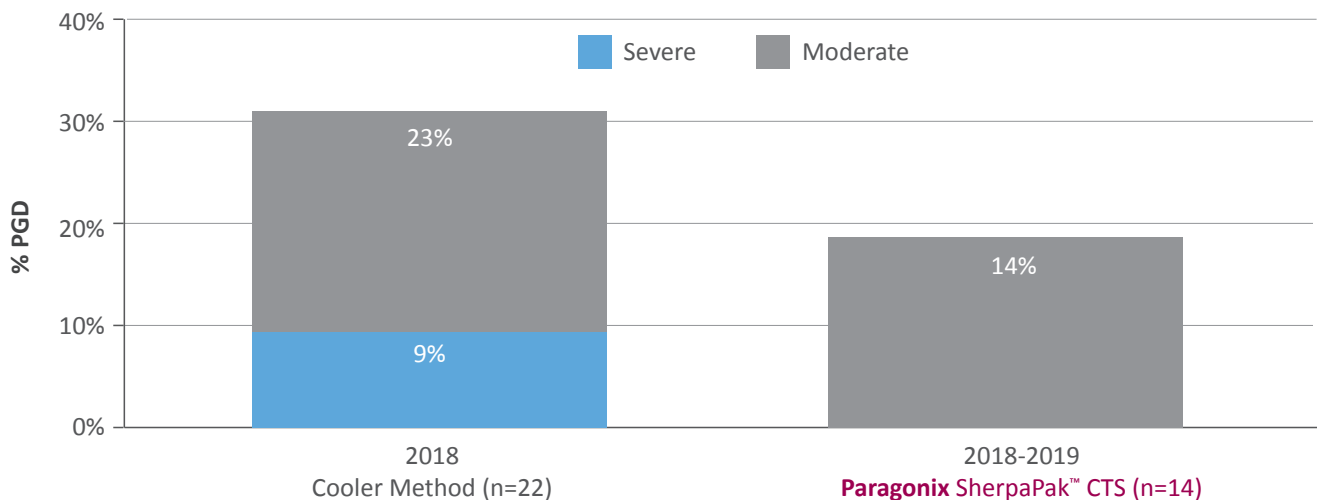


US and EU Clinical Experience			
Paragonix SherpaPak CTS™ Internal Temperature (°C)	Mean: 5.2	Min (Mean): 4.1	Max (Mean): 6.0
Paragonix SherpaPak CTS™ Transport Time (minutes)	Mean: 134	Min: 7	Max: 279*
Total Ischemic Time (minutes)**	Mean: 236	Min: 87	Max: 420
% of Transports where >4 Hours of Total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

- Paragonix SherpaPak™ CTS provides a controlled and consistent temperature outside the range for cold injury (<2°C).<sup>2-4,7</sup>

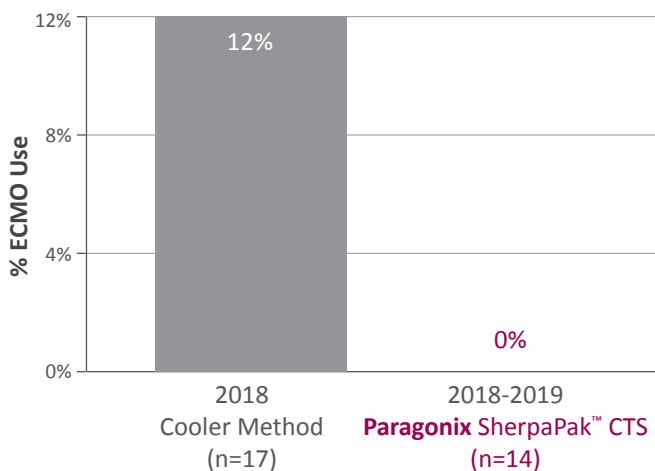
## 71% Reduction in Primary Graft Dysfunction (PGD): Paragonix SherpaPak™ CTS vs. Cooler Method

Paragonix SherpaPak™ CTS has shown a 71% reduction in PGD (moderate and severe) when compared to the cooler method at a single center. There was 0% severe PGD with the use of the Paragonix SherpaPak™ CTS.<sup>6,9</sup>



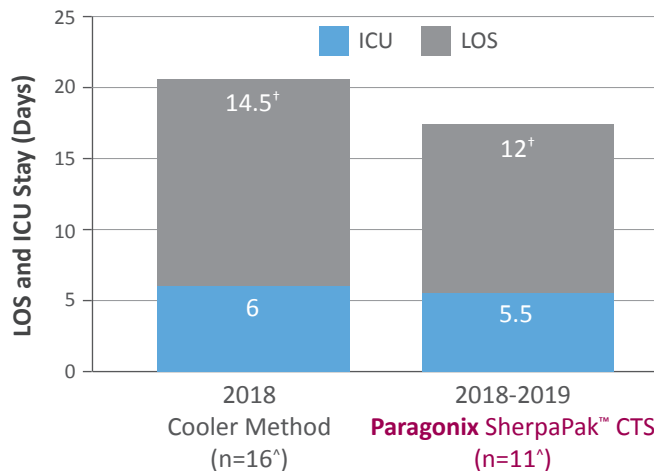
## 0% Incidence of ECMO (Extracorporeal Membrane Oxygenation): Paragonix SherpaPak™ CTS vs. Cooler Method

- Paragonix SherpaPak™ CTS has shown a 0% incidence of ECMO use compared to a 12% ECMO use with the cooler method at a single center.<sup>6,9</sup>
- With the average total cost of ECMO being \$105,035 to \$335,565, the cost savings of going from 12% to 0% ECMO use is \$210,070 to \$671,130.<sup>6,10,11</sup>



## 15% Reduction in LOS (Length of Stay) and ICU (Intensive Care Unit) Stay: Paragonix SherpaPak™ CTS vs. Cooler Method

- Paragonix SherpaPak™ CTS has shown a 15% reduction in LOS (2.5 days<sup>†</sup>) and ICU stay (0.5 days) when compared to the cooler method at a single center.<sup>6,9</sup>
- With the average cost of per inpatient day and ICU day being \$7,500 and \$18,040, the cost savings for a reduction of 2.5 inpatient days<sup>†</sup> and a 0.5 ICU day is \$27,770.<sup>6,12</sup>



## Cost Savings and Reimbursement

- Paragonix SherpaPak™ CTS has shown a cost savings by reducing ECMO use, ICU stay, and LOS at a single center.<sup>6,10-12</sup>
- Paragonix SherpaPak™ CTS is reimbursable via a pass-through charge either through the US Medicare Transplant Cost Report or private payer organ acquisition costs.





# Cardiac Transport System



GUARDIAN is a post-market registry study which will assess patient survival and clinical outcomes of heart transplantation that involves donor heart preservation using the **Paragonix SherpaPak™ CTS**.

**Learn more at:** [www.GuardianHeartRegistry.com](http://www.GuardianHeartRegistry.com)

**Request to enroll at:** [info@guardianheartregistry.com](mailto:info@guardianheartregistry.com)

<b>Principal Investigator</b>	Dr. Andreas Zuckermann, AKH, Vienna, Austria
<b>Co-Investigator</b>	Dr. David D'Alessandro, Massachusetts General Hospital, Boston, MA
<b>Protocol</b>	<b>Paragonix SherpaPak™ CTS</b> for preservation. No change in standard care protocols.
<b>Objectives</b>	Assess clinical parameters in the following time periods: 24 hours, 30 days, 1 year post-implant
<b># of Clinical Parameters Captured</b>	>200
<b># of Centers</b>	No limit
<b>Follow-up Period</b>	12 months

## Ordering, Support and Product Information

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

\*n=37, \*median days, \*LOS sample size only.

1. Rubinsky. Heart Failure Reviews 2003; 8:277-284. 2. Michel et al., Heart, Lung, and Vessels 2015; 7(3):246-255. 3. Ingemansson, et al., Ann Thorac Surg. 1996; 61: 1413-7. 4. Mankad, et al., J Thorac Cardiovasc Surg 1992; 104: 1618-1624. 5. Keon et al. Ann Thorac Surg 1988; 46:337-341. 6. Paragonix SherpaPak CTS International Heart Summit, ISHLT Annual Meeting, April 4, 2019. Note: The experience from a single center may not necessarily represent the experience of other centers. 7. Paragonix Technologies, Inc. Data on file. 8. United States Census Bureau. State Population Totals and Components of Change: 2010-2018. Note: Some states had only had part of the territory included with the cooler method or Paragonix SherpaPak CTS. A visual estimate was made to determine the percentage of population that was included for each group. Downloaded on 04/12/2019 at [https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html#par\\_textimage\\_1574439295](https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html#par_textimage_1574439295). 9. Data collected in comparable time periods. 10. Harvey et al., Appl Health Econ Health Policy 2015; 13:341-357. 11. Costs were rounded up to the nearest \$5 increment. 12. AOR/BOR file accessed on 4/16/19 at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Data-Files.html>.



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