SHERPAPAK®

CARDIAC TRANSPORT SYSTEM

PARAGONIX

Introduction

At Paragonix our mission is to create a new standard for organ preservation and transport that improves patient outcomes worldwide. We strive to protect the ultimate donation with the dignity and safety it deserves to give patients every possible advantage to thrive.

The Paragonix SherpaPak® Cardiac Transport System has preserved over 5000 hearts since start of clinical use in 2018. Currently one of the leading FDA-cleared and CE-marked preservation devices for heart transportation, the Paragonix SherpaPak CTS provides a sterile, temperature and pressure-controlled environment for organs traveling between operating rooms. This award-winning product is now being used by over 120 cardiac transplant centers worldwide and almost 60% of U.S. heart transplant centers.*

The Paragonix SherpaPak® CTS incorporates a novel nested canister system in concert with proprietary thermal cooling to provide physical and thermal protection for donor hearts. All Paragonix Advanced Organ Preservation devices combine clinically-proven, stable cooling techniques with digital tracking and monitoring technologies to provide clinicians complete control and oversight throughout the donor organ journey.

*Based on Paragonix data on file and publicly available U.S. transplant data from http://optn.transplant.hrsa

LEADING DONOR HEART PRESERVATION & TRANSPORT SYSTEM

As of August 2024, nearly 50% of U.S. donor hearts were transported with Paragonix SherpaPak® System*

ISHLT 2020 CONSENSUS STATEMENT ON DONOR HEART PRESERVATION

Warns about contact with ice and cites Paragonix as a new technology to prevent freezing

MULTI-CENTER GUARDIAN-HEART REGISTRY PUBLISHED CLINICAL STUDIES

Significant improvement seen in post-operative outcomes from the use of the Paragonix SherpaPak® system compared to ice storage[1,17]

DELIVERING A NEW STANDARD IN HEART PRESERVATION & TRANSPORT

HISTORIC STANDARD OF CARE STORAGE

PROBLEM

Unpredictable Myocardial Cooling

CAUSE

Rapid Temperature Decrease to Below 2°C

RESULT

- Multi-center clinical study found that average organ temperature during transportation (n=186) was below 2°C, and after 6 hours below 0°C[2]
- Preclinical porcine study found apex temperature below 2°C in 30 minutes and ventricle below 2°C in 150 minutes[3]
- Preclinical canine study found right ventricle, left ventricle and septum below 1°C in 75 minutes and below 0°C in 4 hours[4]

KNOWN RISKS BELOW 2°C

< 2°C: Cold injury[5-8]

< 1°C: Irreversible suppression of diastolic function[9]

< 0°C: Proteins denature[5-8]

PGD PREVALENCE & RISK FACTORS OF TRADITIONAL ICE STORAGE[10]

PGD Prevalence

Study of 317 patients over 5 year period

- 31% (99) classified as PGD
- 12% (39) severe PGD & required MCS

Ischemic Time as a Risk Factor

- PGD associated with longer median donor ischemic time (3.2 vs 2.8 hours, $p < 0.001$)
- 1.8x greater risk of PGD for each additional hour ($p < 0.001$; 95% CI 1.37 - 2.42)

REAL-WORLD DATA

Impact of Controlled Hympothermic Preservation on Outcomes Following Heart Transplantation[11]

THE RISK OF SEVERE PGD

This analysis substantiates the 2014 definition of severe PGD as a clear risk factor for reduced 1 year survival

30, 60, & 365 DAYS POST-TRANSPLANT

The data suggests that severe PGD triggers a sequelae of complications

ADVANCED PRESERVATION

Should be reflected in our PGD consensus as a mitigation strategy

ALMOST 8X

Increase in 1-Year Mortality in Patients with Severe PGD vs No PGD (p=<0.100)[11]

ISHLT DONOR HEART PROCUREMENT CONSENSUS

- Avoid close proximity to ice because of irreversible cell damage
- Freezing injury is an under-appreciated cause of graft failure

"Direct contact of ice with the myocardium may cause freezing. Freezing of any part of the heart is undesirable because freezing and thawing cause irreversible cellular damage"[12]

PARAGONIX SHERPAPAK®
CARDIAC TRANSPORT SYSTEM

TEMPERATURE PROBE
Continuous monitoring of temperature

PURGE MECHANISM
Enables flushing system to remove trapped air pockets for even cooling

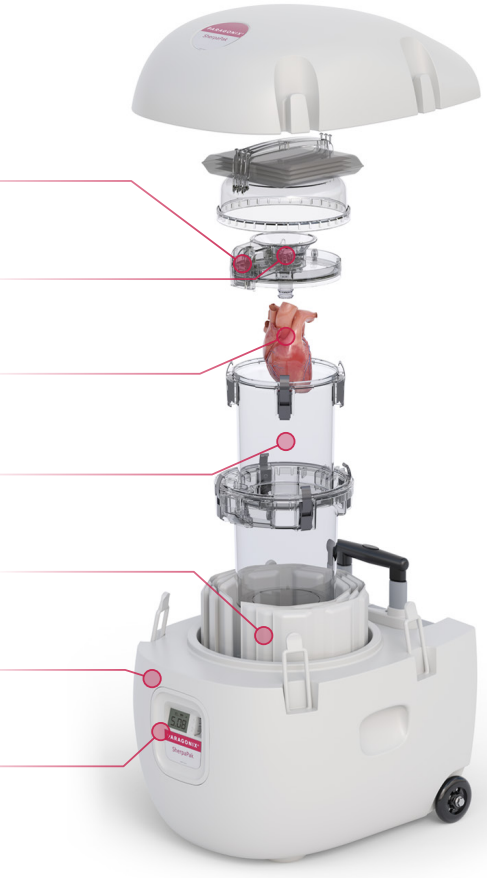
HEART CONNECTOR
Four sizes of heart connector to fully suspend heart immersed in preservation solution

NESTED CANISTER SYSTEM
Pressure controlled and leak-proof rigid canister to safeguard heart

PARAGONIX SHERPACOOL® RIBBONS AND POUCH
Lightweight shipper system is validated to maintain a consistent thermal environment for up to 40 hours

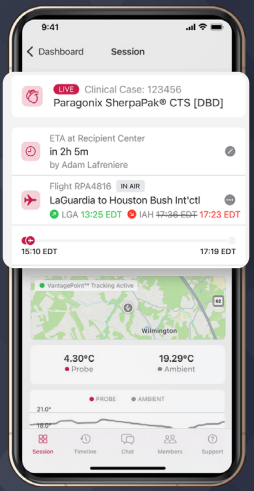
SHIPPER WITH TELESCOPING HANDLE AND WHEEL
Lightweight, easy to handle system designed to fit in standard aircraft and ground vehicles

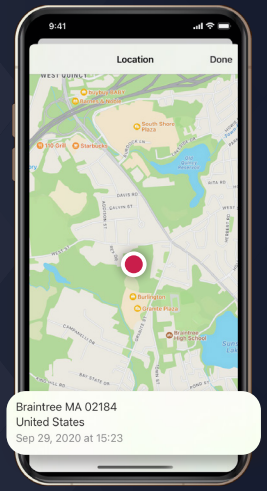
DISPLAY AND BLUETOOTH® DATA TRANSMISSION
Real-time monitoring and data reporting via Bluetooth® connected devices

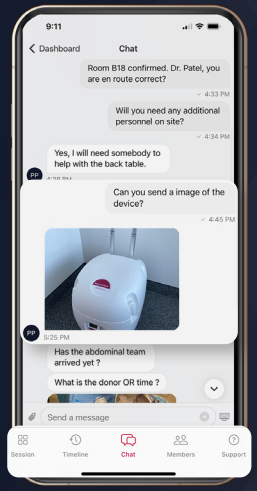


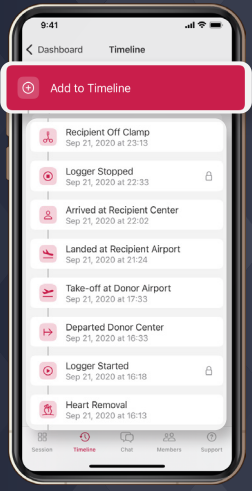
FOLLOW YOUR TRANSPLANT'S JOURNEY FROM BEGINNING TO END

The Paragonix App and Web Portal provides real-time, centralized, secure coordination for transplant teams including pairing with the Paragonix organ transport systems to share organ status with the entire team









ORGAN STATUS

Bluetooth® pairing

LOCATION

GPS tracking

COMMUNICATION

HIPAA compliant messaging

CASE STATUS

Snapshot summaries

GUARDIAN CLINICAL RESULTS[1]

GUARDIANHEART

Improved 2-year Heart Transplant Survival with Moderate Hypothermic Donor Heart Preservation

Scott Silvestry, Dan M. Meyer, Si M. Pham, Jeffrey P. Jacobs, Yasuhiro Shudo, Jacob Schroder, Marzia Leacche, Christopher M. Sciortino, Hannah Copeland, Maria E. Rodrigo, Koji Takeda, Masashi Kawabori, Balakrishnan Mahesh, Liviu Klein, Andrija Vidic, Snehal R. Patel, David A. D'Alessandro

KEY FINDINGS

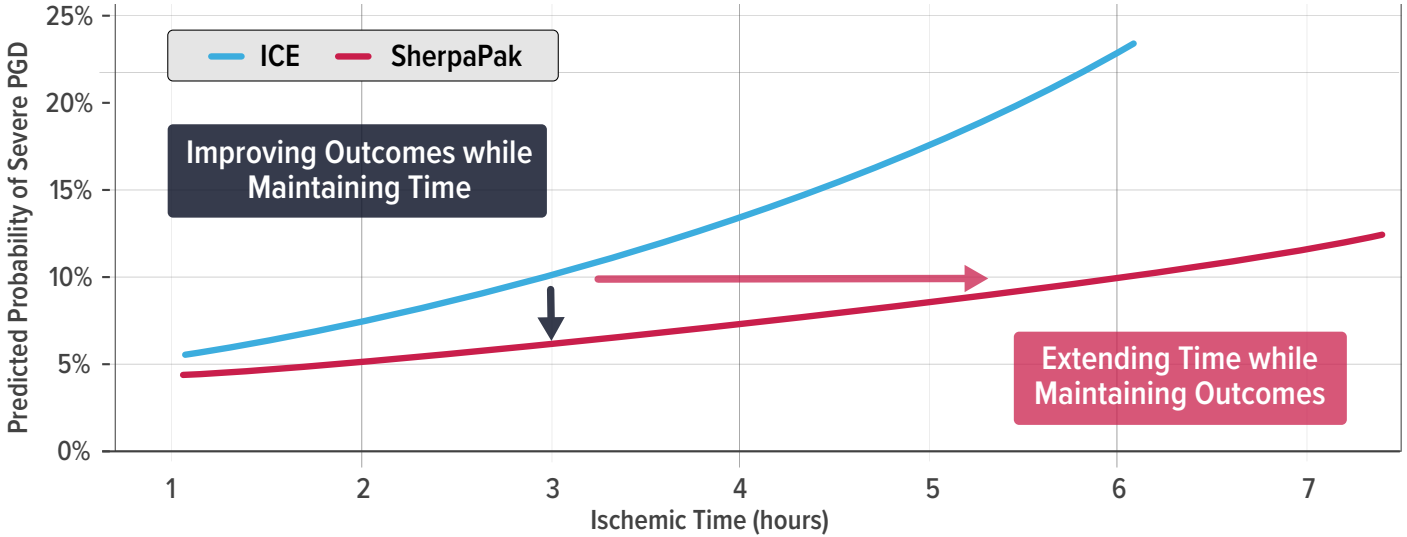
- Utilization of Paragonix SherpaPak CTS for organ preservation is associated with significant improvements in post-transplant outcomes and superior 2-year survival
- The first time any device has ever demonstrated statistically significant improvements in 2-year survival in heart transplantation
- SherpaPak CTS appears to be associated with a significant attenuation of historical risks associated with cold ischemic time

		ICE	PARAGONIX SHERPAPAK	*P*-VALUE
SURVIVAL	2-year Survival (%)	89.5%	**94.3%**	0.040
PGD	PGD Severe (%)	11.0%	**5.5%**	0.010
POST-TRANSPLANT MCS	All Post Tx MCS (%)	27.9%	**19.1%**	0.006
	Newly placed ECMO/VAD Post Tx (%)	12.7%	**7.7%**	0.036
RV FUNCTION	RV Normal (24 hours post)	45.8%	**54.5%**	0.028
	RV Severely diminished	9.8%	**5.5%**	0.050

Comparison of Paragonix System to Ice Storage, Paragonix data on file. GUARDIAN is a registered clinical study funded and administered by Paragonix Technologies. The data from the registry is descriptive, not statistically powered, and not pre-specified. The information should be interpreted accordingly.

IMPROVING OUTCOMES TO ALL ISCHEMIC TIMES[1]

Predicted Probability of Severe PGD at Ischemic Time Intervals



THERE IS NO ISCHEMIC TIME WHERE ICE IS BENEFICIAL OVER SHERPAPAK

For example, maintaining an ischemic time of 3 hours, we see a probability of Severe PGD cut almost in half

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CLINCAL ANALYSIS SHOWING REDUCTION IN SEVERE PGD
UTILIZING PARAGONIX SHERPAPAK

	ICE STORAGE		PARAGONIX SHERPAPAK CTS			
GUARDIAN-Heart Analysis	Severe PGD Percentage	N	Severe PGD Percentage	N	*p*-value	Percent Reduction in Severe PGD in SherpaPak CTS Cohort
2024 ISHLT Overall US Population[1]	10.8%	566	6.8%	695	**0.015**	**37.0%**
2024 ISHLT Propensity Matched Baseline[1] (Matched on site, era, ischemic time, donor age, LVAD)	11.0%	362	5.5%	362	**0.010**	**50.0%**
2023 JHLT Overall US Population[11]	10.4%	453	6.6%	560	**0.039**	**36.5%**
2023 JHLT Propensity Matched Baseline[11] (Matched on site, era, ischemic time, donor age, LVAD)	12.1%	281	6.0%	281	**0.018**	**50.4%**
2023 ASAIO Overall US Population[14]	10.2%	150	5.4%	150	**0.032**	**47.0%**
2023 ASAIO Propensity Matched Baseline[14] (Matched on site, era, ischemic time, donor age, LVAD)	12.0%	150	4.0%	150	**0.011**	**67.0%**
Extended Criteria Donors*[15]	13.9%	137	6.2%	193	**0.022**	**55.4%**
Recipients by Bridge-to-Transplant Strategy[16]	10.2%	354	6.2%	421	**0.046**	**39.2%**
LVAD Patients[17]	14.0%	178	5.4%	149	0.01	61.4%

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*Met the criteria of either 4 hour total ischemic time or 2 hour ischemic time plus one of the following co morbidities Donor 55 y/o, Donor downtime 20 min, Donor history of diabetes, Donor LVEF 40 50 Donor LVH 12 16 mm, Donor luminal irregularities

GUARDIAN-HEART CLINICAL RESULTS

Post-Operative Cost Benefit Analysis[13]

GUARDIAN registry data was analyzed to evaluate post-operative cost differences from improvements in clinical outcomes and their associated reductions in clinical interventions.

~$26,000

IN AVERAGE SAVINGS PER PATIENT

Cost Differences: Paragonix SherpaPak vs Ice Storage

"The use of SCTS (SherpaPak) in the US may be clinically and cost beneficial as a donor heart preservation system versus ICS (ICE), in particular as the use of SCTS appears to lead to improved post-transplant outcomes related to reductions in incidence of severe PGD and MCS utilization."

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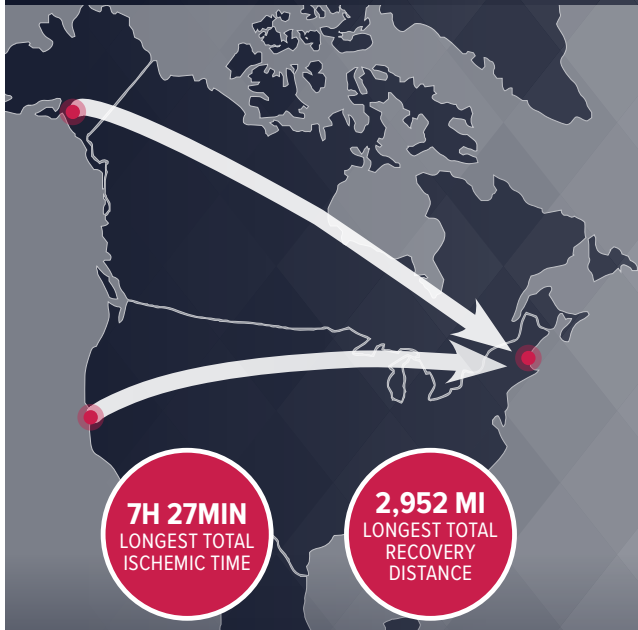
EXPAND PROGRAM RANGE[18]

Massachusetts General Hospital has utilized the Paragonix SherpaPak while expanding their reach all the way to Alaska and California



Indications for Use: SherpaPak CTS is indicated for organ storage times up to 4 hours. Donor hearts exceeding clinically accepted static hypothermic preservation times should be evaluated by the transplant surgeon to determine transplantability.

References

1. Silvestry et al., ISHLT Presentation 2024
2. Horch et al., Transplant Proceed 2002
3. Validation data on file with Paragonix Technologies
4. Hendry et al., J Thorac and Cardiovasc Surg 1989
5. Michel et al. Ann Transplant 2014
6. Michel et al. Ann Transplant 2015
7. Ingemansson et al., Ann Thorac Surg 1996
8. Mankad et al., J Thorac and Cardiovasc Surg 1992
9. Keon et al., Ann Thorac Surg 1988
10. Nicoara et al., Am J Transplant 2016
11. D'Alessandro et al., J Heart Lung Transplant. 2024; 43:1153–1161
12. Copeland et al., J Heart Lung Transplant 2020
13. Voigt et al., ASAIO Journal 2023; 69;345–349
14. Shudo, Y. et al., ASAIO Journal 2023; 69;993–1001
15. Moayedifar et al., J Heart Lung Transplant. 2024 Apr;43(4):673-680
16. Silvestry et al., ASAIO J. 2024 May; 70(5):388-395.
17. Lerman et al., Circulation HF. 2024 May;17(5)
18. S. Li et al. JHLT Open 2024;4:100062

Indications for Use: The Paragonix SherpaPak® Cardiac Transport System (CTS) 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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