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.

Paragonix SherpaPak® Cardiac Transport System has preserved over 800 hearts since start of clinical use in 2018. Currently the only FDA cleared and CE marked preservation device for heart transportation, Paragonix SherpaPak CTS provides a sterile, temperature and pressure-controlled environment for organs traveling between operating rooms. This award-winning product is designed to be easy-to-use in stressful, clinically demanding environments where there is no room for mistakes.

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 temperatures are monitored throughout the organ journey via a Bluetooth® connected monitoring app.
DELIVERING A NEW STANDARD IN HEART PRESERVATION & TRANSPORT
PROBLEM
Unpredictable Myocardial Cooling

CAUSE
Rapid Temperature Decrease to Below 2°C

RESULT
• Multi-center clinical study found average organ temperature during ice cooler transportation (n=186) was below 2°C and below 0°C after 6 hours¹

• Preclinical porcine study found apex temperature below 2°C in 30 minutes and ventricle below 2°C in 150 minutes²

• Preclinical canine study found right ventricle, left ventricle and septum below 1°C in 75 minutes and below 0°C in 4 hours³

KNOWN RISKS BELOW 2°C
< 2°C: Cold injury⁴-⁷
< 1°C: Irreversible suppression of diastolic function⁸
< 0°C: Proteins denature⁴-⁷
PGD PREVALENCE & RISK FACTORS

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)

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

PGD REPRESENTS A SIGNIFICANT EXPENSE

$324,226
MCS average cost $324,226 +/-140,751

$156,793
No MCS average cost $156,793+/−47,359

$7,132,980
Total cost for patients requiring MCS over 2 years

16.1%
Of patients required MCS for PGD but accounted for...

25.5%
Of total institution expenditures for heart transplantation

“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.”
PARAGONIX SHERPAPAK®
CAR DiAC 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
Consistent storage environment validated to maintain temperature over 40 hours

SHIPPER WITH TELESCOPING HANDLE AND WHEELS
Light-weight, easy to handle system design 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

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 to track organ conditions

LOCATION
GPS tracking of procurement team en route from the donor center

COMMUNICATION
At-a-glance graphic status trackers provide a snapshot summary of timing of key events in the transplant

CASE STATUS
HIPAA compliant messaging and communications to keep the procurement team, OPO, donor hospital, and recipient team informed
GUARDIAN CLINICAL RESULTS

First Report of the GUARDIAN Registry: An International Consortium Examining the Effect of Controlled Hypothermic Preservation in Heart Transplantation
D.D'Alessandro, J.Philpott, T. Boeve, S. Pham, A. Zuckermann

KEY FINDINGS

Heart preservation utilizing the Paragonix SherpaPak CTS compares favorably to ice storage in this registry analysis

- Early clinical outcomes, including PGD rates and ICU length of stay are improved despite unfavorable donor and recipient characteristics
- Mid-term survival is maintained despite these important differences
- Additional patients and analysis are needed to understand the impact on survival of matched populations

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<thead>
<tr>
<th></th>
<th>ICE</th>
<th>PARAGONIX SHERPA PAK</th>
<th>P-VALUE</th>
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<tbody>
<tr>
<td><strong>WAITLIST</strong></td>
<td>Median Time on Waitlist (days)</td>
<td>90</td>
<td>42</td>
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<tr>
<td><strong>TRANSPORT</strong></td>
<td>Total Ischemic Time (min)</td>
<td>176.5</td>
<td>208</td>
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<td><strong>TRANSPLANT</strong></td>
<td>Cardioversion (%)</td>
<td>26.0%</td>
<td>15.4%</td>
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<td><strong>POST-TRANSPLANT</strong></td>
<td>PGD Severe</td>
<td>14.1%</td>
<td>6.5%</td>
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<td></td>
<td>Post Tx ICU LOS (days)</td>
<td>14.4 ± 22.1</td>
<td>10.4 ± 12.7</td>
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<tr>
<td></td>
<td>LVEF at Discharge (%)</td>
<td>61.9 ± 8.0</td>
<td>64.3 ± 8.2</td>
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GUARDIAN is a registered clinical study (https://clinicaltrials.gov/ct2/show/NCT04141605). At the time of this analysis, GUARDIAN contained data from 5 sites on 223 patients (99 ice transports and 123 Paragonix SherpaPak CTS transports). The data from the registry is descriptive, not statistically powered, and not pre-specified. The information should be interpreted accordingly.
GUARDIAN CLINICAL RESULTS

Ischemic Time Analysis

Data demonstrated that a controlled hypothermic transport system provides reliable preservation for cardiac allografts especially when longer ischemic times are required.

Key Findings

- Significantly longer ischemic time (31 minutes longer median) in Paragonix cohort
- Significantly shorter ICU stay (3 days shorter median) in Paragonix cohort

Patients with >3 hours total ischemic time

Cases utilizing the Paragonix Sherpapak CTS showed a significant decrease of proportion of patients discharged from the ICU in 2 weeks or more (p=0.048) and significantly increased the number of patients discharged in under a week (p=0.0002)
GUARDIAN CLINICAL RESULTS
Impact Multiple Stages of The Transplant Process

Figures represent the percentage difference observed between transplant recipients of donor hearts preserved by Paragonix SherpaPak CTS and ice storage, as reported in the GUARDIAN registry.

-54% Waitlist days
+18% Total Ischemic Time
-41%* Cardioversion
-54%** Severe PGD
-28% ICU LOS
+4% LVEF

*Numerical trend, does not achieve statistically significance, p=0.067 **Numerical trend, does not achieve statistically significance, p=0.071
GUARDIAN CLINICAL RESULTS

Post-Operative Cost Benefit Analysis

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

$20,000
IN AVERAGE SAVINGS PER PATIENT (P=0.046)

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<tr>
<th>Cost Type</th>
<th>PGX</th>
<th>ICE</th>
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<tr>
<td>ICU Costs (N=72)</td>
<td>$25,093</td>
<td>$39,093</td>
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<tr>
<td>TOTAL COSTS (ALL PATIENTS) (N=72)</td>
<td>$44,386</td>
<td>$63,080</td>
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<tr>
<td>TOTAL COSTS (PGD ONLY PATIENTS)</td>
<td>$83,593</td>
<td>$128,809</td>
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Centers around the world have reported the ability to access more donor hearts at greater distances. A major center in California grew to a record number of transplants and expanded their reach to Alaska, Missouri, the Dakotas, and Texas.

Disclaimer: SherpaPak CTS approved for use up to 4hrs. Extension of this period based on judgement of individual attending physicians.
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.