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: 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)

Preventing Cold Injury in Transplants

Quick Reference Steps: Organ Removal and Transit

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

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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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 transport and eventual transplant 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.


** Patents issued and pending
Paragonix SherpaPak™ 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:

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

Note: These data are not averages. This is a representative example.

Apex

Temperature °C

- 2
- 4
- 6
- 8

Transport Time / Hours

- 0.50
- 1.0
- 1.5
- 2.0
- 2.5
- 3.0
- 3.5
- 4.0
- 4.5

n=7

n=49

Note: Data average as of March 2019. Graph does not reflect total ischemic time.

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.”

“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!”
## Product Highlights

<table>
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<th>Feature</th>
<th>Benefits</th>
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<td><strong>Paragonix SherpaPak™ Cardiac Transport System with CoolSafe™ Technology</strong> – 38 patents(^a)</td>
<td>Consistent temperature range prevents cold injury</td>
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<td><strong>Temperature Probe</strong></td>
<td>Continuous monitoring of temperature</td>
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<td><strong>Heart Connector</strong> – for most aortic diameters</td>
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<td><strong>Dual-Canister with Carrying Handle</strong></td>
<td>Easy to carry, pressure-controlled, leak-proof and rigid to safeguard the heart</td>
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<td>Real-time monitoring (Fig. 1) and data reporting via Bluetooth(^\circ) with mobile devices (Fig. 2)</td>
</tr>
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</table>

Fig. 1: Digital display of temperature.

Fig. 2: Actual data report example of transport time and temperature.
**Validation Data: Paragonix SherpaPak™ CTS vs. Cooler Method**

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™ CTS**

![Graph showing temperature changes over time for Paragonix SherpaPak™ CTS and Cooler Method](image)

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**US and EU Clinical Experience**

<table>
<thead>
<tr>
<th>Description</th>
<th>Mean</th>
<th>Min (Mean)</th>
<th>Max (Mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paragonix SherpaPak CTS™ Internal Temperature (°C)</td>
<td>Mean: 5.2</td>
<td>Min (Mean): 4.1</td>
<td>Max (Mean): 6.0</td>
</tr>
<tr>
<td>Paragonix SherpaPak CTS™ Transport Time (minutes)</td>
<td>Mean: 134</td>
<td>Min: 7</td>
<td>Max: 279</td>
</tr>
<tr>
<td>Total Ischemic Time (minutes)**</td>
<td>Mean: 236</td>
<td>Min: 87</td>
<td>Max: 420</td>
</tr>
<tr>
<td>% of Transports where &gt;4 Hours of Total Ischemic Time**</td>
<td>43%</td>
<td></td>
<td></td>
</tr>
<tr>
<td># Adverse Events / # Device Failures</td>
<td>0 / 0</td>
<td></td>
<td></td>
</tr>
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- **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

**Cooler Method**

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

**Clinical Feedback:**

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

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<th>Time / Hours</th>
<th>Paragonix SherpaPak™ CTS</th>
<th>Cooler Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=7)</td>
<td>(n=7)</td>
</tr>
<tr>
<td>Temperature °C</td>
<td>2 4 6 8</td>
<td></td>
</tr>
<tr>
<td>Apex</td>
<td>0.50 1.0 1.5 2.0</td>
<td></td>
</tr>
<tr>
<td>Ventricle</td>
<td>2.5 3.0 3.5 4.0 4.5</td>
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Note: Data average as of March 2019. Graph does not reflect total ischemic time.
Paragonix SherpaPak™
Cardiac Transport System

Quick Reference Steps: Organ Removal and Transit

**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.

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www.ParagonixTechnologies.com

Ordering, Support and Product Information

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2. Data on file. 3. Michel et al., Heart, Lung, and Vessels 2015; 7(3):246-255. 4. Please refer to Instructions for Use for full prescribing information. 5. Patents issued and pending. 6. n=37

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