

PARAGONIX®

# Paragonix SherpaPak™<sup>1, 2, 3, 4</sup>

## Cardiac Transport System

Commercially available for the transport and storage of donor hearts.



**A single-use, disposable cold storage device intended to standardize and control donor organ preservation and transport**

### Paragonix SherpaPak™

- Donor heart preservation and transport device
- Use with any FDA-cleared preservation solution
- Minimizes temperature fluctuations
- Maintains constant preservation temperature between 4–8°C
- Single-use to standardize organ transport and enhance process consistency
- Reduces cross-contamination liabilities of re-usable transport coolers

<sup>1</sup> Patents issued and pending

<sup>2</sup> Caution: Federal (US) law restricts this device to sale by or on the order of a licensed health care practitioner

<sup>3</sup> Please refer to Instructions for Use for full prescribing information

<sup>4</sup> Cleared indication is for 4 hour use. Data on File.

# Paragonix SherpaPak™

www.paragonixtechnologies.com



Paragonix SherpaPak™ insulated shipper:  
Thermal stability validated for 12+ hours  
at ambient and extreme temperatures



Disposable cold packs:  
Non-toxic, engineered for high latent  
heat storage in the 4–8°C range



Sterile, rigid storage canister set:  
Inner organ canister holds 4 L with real-  
time preservation temperature sensor



#### Indicated for donor heart preservation and transportation

- Conventional ice chests are an uncontrolled method of donor organ transport
- All components are fully validated
- Use with any FDA-cleared, effective preservation solution indicated for donor hearts



#### Maintains safe organ preservation temperature

- No temperature gradients across donor hearts
- Continuously measures and displays temperature and ischemic time during storage and transport
- Storage temperature is validated for 12+ hours



#### Complete immersion of donor organ in solution

- Donor heart is fully immersed in preservation solution
- Two rigid sterile canisters plus Paragonix SherpaPak™ shipper provide triple barrier protection of organs
- Meets or exceeds UNOS/AOPO Organ Packaging Guidelines



#### Monitor and record organ temperature

- Continuously measures and displays temperature and ischemic time during storage and transport
- Temperature report downloads to your phone or tablet
- Communicates via Bluetooth with mobile devices

# Current Heart Storage

# Paragonix SherpaPak™

Prepare heart for transport

Isolation bags: not validated for heart preservation

Place heart in isolation bag. Add approved solution. Tie bag.

"Tying" top of bag: not validated to prevent solution loss or leakage

Place isolation bag in second isolation bag. Add ice slush or ice water per guidelines. Tie bag.

Ice slush mix: not validated to comply with solution's required temperature range

Place isolation bag in third isolation bag. Add ice slush or ice water per guidelines. Tie bag.

Ice chests: Not validated for heart preservation

Place isolation bags in cooler. Cover with ice slush or ice water per guidelines.

Concerns about fluid loss, sterility, temperature variance

Place heart in canisters. Add approved solution. Seal lid.

Two leakproof canister seals: validated and meet or exceed UNOS regulations

Insert cold packs. Put canisters in Paragonix SherpaPak™

All components: validated for cardiac preservation

Prepare heart for implantation

No information on control of temperature. Ischemic time not monitored.

Hypothermic management unknown

Liability for possible disease transmission if reused

Reprocess for pathogen disinfection

Restock cooler into inventory

Hypothermic management at 4-8°C

Temperature and ischemic time monitored and displayed

Single-use, disposable system

**PARAGONIX®**

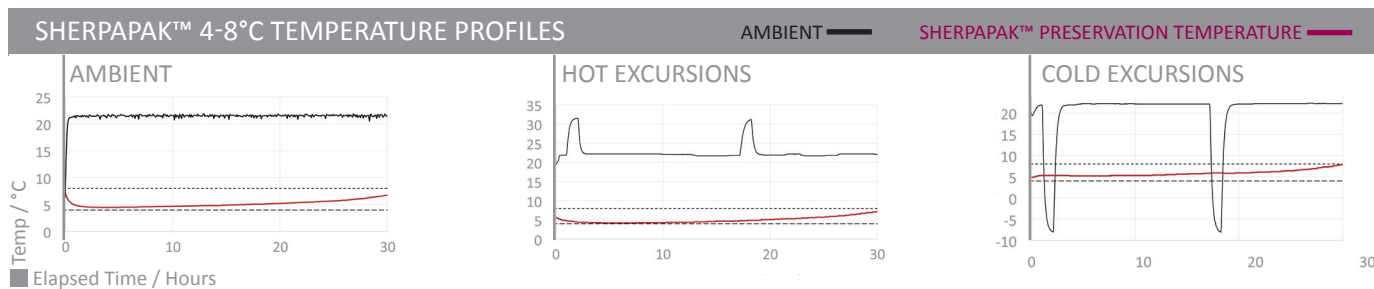
# Paragonix SherpaPak™

## Cardiac Transport System

### Validation Studies

#### 1. THERMAL MAINTENANCE BETWEEN 4 - 8°C

Thermal qualification test results demonstrate that the Paragonix SherpaPak™ Cardiac Transport System can reliably maintain approved preservation fluid storage temperatures for the donor heart and is safe and effective for its intended use. Paragonix SherpaPak™ maintains a 4-8°C temperature range validated for up to 12+ hours (Michel et al. 2015: Innovative Cold Storage using the Paragonix Sherpa Pak™. Heart, Lung and Vessels; Data on File).



#### 2. TRANSPORTATION TESTING ACCORDING TO ASTM D4169-09

Paragonix SherpaPak™ has been tested in accordance with ASTM D4169-09 (Standard Practice for Performance Testing of Shipping Containers and Systems)<sup>6</sup>. The results show the System does not exhibit any damage or leakage during transportation. Paragonix SherpaPak™ meets the transportation requirements for organ transport products.

#### 3. BIOCOMPATIBILITY FOR MATERIALS IN DIRECT & INDIRECT ORGAN CONTACT PER ISO 10993-1:2009

Paragonix SherpaPak™ materials, body contact (i.e., indirect and direct contact with the donor organ), and duration of contact (<24 hours) were assessed using ISO 10993-1:2009 (Biological Evaluation of Medical devices).

Test	Ref. Standard	Results
Cytotoxicity	ISO 10993-5:2009	Passed
Sensitization	ISO 10993-10:2010	Passed
Irritation/Intra-cutaneous Reactivity	ISO 10993-10:2002	Passed
Hemolysis	ISO 10993-4:2002/2006 and ASTM F756	Passed
USP Pyrogen Study	ISO 10993-11:2006	Passed
Systemic Toxicity	ISO 10993-11:2006	Passed
Genotoxicity	ISO 10993-3:2003	Passed

#### 4. LEAK TESTING

Paragonix SherpaPak™ canisters were tested for leaks in accordance with ASTM F2391-05 - Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas. The results show the dual canisters' seal integrity will protect the donor organ and is safe for the intended use.

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<sup>5</sup> According to "Level II" assurance level

