

PARAGONIX®

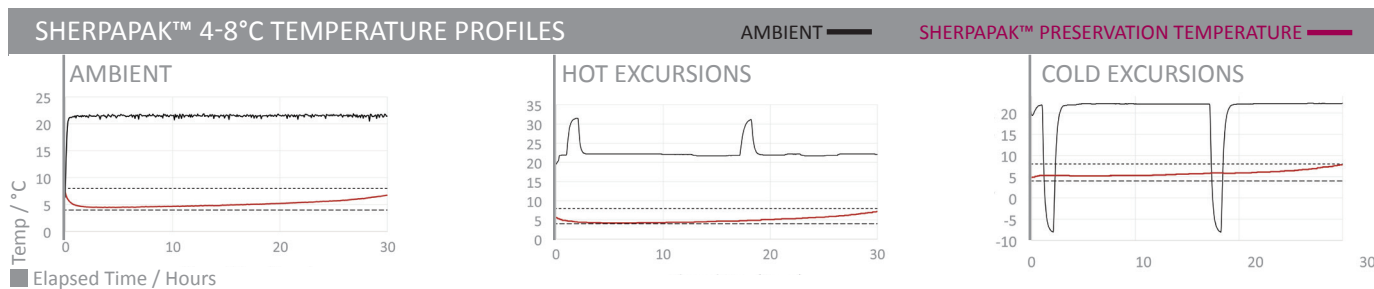
Paragonix SherpaPak™

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)⁶. 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.

¹ Patents issued and pending

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

³ Please refer to Instructions for Use for full prescribing information

⁴ Cleared indication is for 4 hour use. Data on File

⁵ According to “Level II” assurance level

