PARAGONIX®
EVERY POSSIBLE ADVANTAGE™

GUIDE TO THE QUALITY AND SAFETY OF **ORGANS FOR TRANSPLANTATION**

European Committee
(Partial Agreement)
on Organ Transplantation
(CD-P-TO)

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Packaging & Transportation of Organs

The procurement team should provide all necessary blood tubes, containers and transport coolers. The organ(s) should be stored in the same solution used for perfusion. Triple sterile packing is preferred. The organ(s) are stored directly in perfusion fluid in the innermost container with the exclusion of air, with a second solution (cooled to 4 °C in the case of cold storage) in the middle container, again with the exclusion of air. Both containers are then inserted into a third container without fluid or air (as air expands at altitude, its inclusion can cause rupture of the containers if organs are transported by aircraft). The package is placed in an insulated organ transport box (or outermost container) to achieve good thermoregulation, with sufficient cooling elements or crushed ice in case of cold storage. Deviation from triple packing may be appropriate if the packing system used is certified and validated by the responsible authorities.

The packaging material should be inert, impermeable and sterile. All packaging materials should be validated for their intended use, with particular attention to the maintenance of temperature within the desired range and for the specified time. The outer container should be thermally insulated and made of a material robust enough to prevent leakage of con-tents and to withstand shocks, atmospheric pressure changes and other possible conditions during the course of transportation. In the case of cold storage, it must ensure that the organ is kept within a temperature range of 1-6 °C. The innermost container should contain sufficient fluid to prevent direct contact between the organ and cooling elements or crushed ice (produced from uncontaminated water). Transplant-organ containers should be labelled externally with all the necessary identification details, while preserving the anonymity of the donor. Labelling should include, as a minimum, the following:

1. Anonymised donor identification
2. Contents of the package, including the type of organ/ tissue and, where appropriate, whether it is the right or left organ.
3. Address of destination, including details of the person to be notified upon arrival.
4. Address of the shipping institution and details of the person to be to be notified of unexpected complications
5. Recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position, as well as 'handle with care' and 'Human Organ for Transplantation' marks.

Before release for transportation, it is mandatory to check the contents of the package and to ensure that all relevant information and documentation is provided, along with the appropriate labelling, as well as any additional donor-relevant attachments (e.g. spleen or lymph nodes for tissue-typing and cross-matching, sera and plasma samples and the 'vessel toolkit', where applicable). There are vessels and potentially other donor material that will be essential when the organ is to be transplanted. These vessels and other material should be clearly identified on the package label. The outer organ transport box should be properly sealed.

The surgeons and coordinators responsible for the organ retrieval and transplantation should be notified of the progress and results of all procedures pertinent to the organ procurement operation. In cases of delay or unexpected findings, the recipient centers should be informed.

1. Donor identification number
2. Time and date of declaration of death of the donor
3. Blood group of donor
4. Place of donation
5. Time and date of donation
6. Time of perfusion or organ preservation
7. Anonymous medical details of the donor and retrieval process
8. Detailed descriptions of the organ anatomy and a full report of any damage
9. Type and volume of preservation fluid and start of cold ischaemia time (and for DCD: time from circulatory arrest until cold perfusion in warm ischaemic time)
10. Members of the retrieval team

Conclusion

Organ preservation, procurement and transport are key parts of the transplantation pathway. It is therefore vital that countries have an organ procurement, preservation and transport programme that ensures that the safest, highest-quality organs are offered for transplant, and that organs are retrieved in a timely and coordinated fashion by experienced personnel whose objective is to optimize all organs retrieved for transplantation.

Organ Preservation Redefined

The Paragonix SherpaPak™ Cardiac Transport System (CTS) safeguards hearts during the journey from donor to recipient patient. Our device incorporates clinically proven and medically trusted cold preservation techniques in a novel suspension system to provide unprecedented physical and thermal protection. Paragonix SherpaPak™ CTS is the only commercially available FDA cleared and CE marked medical device for heart transportation.

Controlled temperature range

4-8°C

Protects heart from cold injuries

Heart is protected and immersed in preservation solution

Homogenous and stable organ pressure

Real time data monitoring & reporting

FDA CE

FDA cleared and CE mark

Preservation Advantage

	CTS	Ice Cooler
Protects hearts from the damaging temperature zones	● YES	○ NO
CoolSafe™ technology provides a consistent temperature range and prevents cold injury	● YES	○ NO
Heart fully suspended and immersed in preservation solution for even cooling	● YES	○ NO
Pressure-controlled, leak-proof, and rigid canisters safeguarding the heart	● YES	○ NO
Real-time monitoring & data reporting to your mobile device for quality management	● YES	○ NO
FDA cleared and CE marked medical device Class 2A Directive 93/42/EEC	● YES	○ NO
Thermal qualification testing between 4-8°C	● YES	○ NO
Transportation testing according to ATSM D4169-09	● YES	○ NO
Biocompatibility for materials in direct & indirect organ contact per ISO 10993-1:2009	● YES	○ NO
Leak testing in accordance with ASTMF2391-05	● YES	○ NO

Paragonix SherpaPak™ CTS

CoolSafe™ Technology

Maintains a controlled preservation temperature between 4–8°C, incorporating clinically proven and medically trusted cold preservation techniques. All components are fully validated and covered by over 30 patents.

Temperature Probe

Continuously measures heart solution temperature during storage and preservation.

Heart Connector

Heart fully suspended and immersed for even cooling in preservation solution. Available for most aortic diameters.

Dual Canister

Easy to carry, pressure controlled, leak-proof and rigid to safeguard the heart.

Bluetooth® Data Transmission

Real-time Bluetooth® reporting to mobile devices.

Paragonix SherpaCool™ Ribbons

Consistent storage temperature validated for 40+ hours

Datalogger Display

Continuously displays temperature during storage and preservation.

ORDERING & SUPPORT

ORDERS: eu-orders@paragonixtechnologies.com

SUPPORT: eu-support@paragonixtechnologies.com

Indications for Use: The Paragonix SherpaPak™ Cardiac Transport System 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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