

National Standard Operating Procedures

Packaging, Labelling, Storage and Documentation of Deceased Donor Vessels

Version 2.0 ATCA-TSANZ SOP 003/2016



Australian Government
Organ and Tissue Authority



T • S • A • N • Z
THE TRANSPLANTATION SOCIETY
OF AUSTRALIA AND NEW ZEALAND



Australasian Transplant
Co-ordinators
Association Inc.

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I. Background

The use of deceased donor vessels retrieved in the multi-organ donor setting forms part of the standard practice of solid organ transplantation, particularly within the abdomen. For many years, donor vessels have been used to facilitate the implantation of liver, pancreas and renal allografts.

II. Purpose

This protocol outlines the procedures, and the underlying principles, in relation to the packaging, labelling, storage, usage, tracking and documentation of donor vessels retrieved from deceased patients.

These procedures are in place to maximise patient safety and avoid risks. Adherence to these procedures standardises practice across Australia and New Zealand.

III. Scope

This protocol applies to donor vessels retrieved in the deceased organ donor setting.

The protocol does not apply to any other human tissues involved in transplantation such as corneas, musculo-skeletal tissue, heart valves and skin.

IV. Responsibility

- a. The responsibility for review of this document lies with the Transplantation Society of Australia and New Zealand (TSANZ) Donor Surgeons and Donor Coordinators Advisory Committee (DSDCAC) and should be reviewed every 3-5 years.
- b. Heads of transplant units, the Organ and Tissue Authority (OTA) through the DonatLife State and Territory Medical Directors, Managers of DonatLife Agencies and New Zealand Donation Service (NZDS) have the responsibility for ensuring that relevant staff under their supervision utilise this Standard Operating Procedure (PROTOCOL).
- c. The transplant centre is responsible for the re-labelling; storage of donor vessels; maintaining the appropriate Donor Vessel Log Record; discarding of unused donor vessels; completing the Donor Vessel Log Record and notifying the donor DonatLife Agency or NZDS of outcomes by return fax.
- d. It is the responsibility of each DonatLife Agency and NZDS to commence the TSANZ/ATCA Donor Vessel Tracking Form and ensure it accompanies the donor organ(s) and vessel(s) to the recipient hospital.
- e. After 14 days, it is the responsibility of each DonatLife Agency and NZDS to contact the recipient hospital to arrange for the completed TSANZ/ATCA Donor Vessel Tracking Form to be sent back to the DonatLife Agency home state/territory to be filed. It should identify and document the use and disposal of any vessels retrieved for transplantation purposes.
- f. It is the responsibility of all retrieval coordinators to perform the functions outlined above according to individual state practice.
- g. It is the responsibility of each transplant unit to ensure that a Vessel Log Record is maintained in the transplant operating theatre.

V. Consent for Donor Vessel Retrieval and Use

The consent process for donor vessels in each state and territory varies. It is important to note the following differences between jurisdictions when applying this protocol.

All jurisdictions with the exception of the Northern Territory (NT) and South Australia (SA) state that if consent is given, blood vessels can be removed for the purpose of transplantation of the tissue into the body of a living person. The NT consent form says for the purpose of transplantation (only) and the SA form says for transplantation and/or research purposes. They do not specifically say, 'into the body of a living person'.

VI. Processes, Procedures and Documentation

1. Retrieval, packaging and labelling of donor vessels

It is routine for arterial and venous grafts to be procured for liver and whole pancreas transplantation. If the liver is split, arterial and venous grafts should accompany both portions of the liver. It is recommended that the whole length of the common and external iliac artery and vein be retrieved for liver extension grafts.

If the liver has been split and the pancreas has been procured for whole pancreas transplantation, three sets of donor vessel packages will be required.

2. Surgical process

Vessels are placed in containers with preservation solution and are triple packaged. The outer package is labelled with a vessel ID tag (**Appendix 1**).

The vessel packages are placed into the ice in the same transport container as the relevant organ, ensuring that both the organ and vessel packages are completely surrounded and covered by ice.

The vessels must be packaged SEPARATELY to the organ i.e. vessels must not be placed inside the bag with the organ.

3. Documentation to accompany donor vessels for transport

The donor/organ documentation that accompanies the organ and donor vessels is:

- a. Donor blood group
- b. Donor serology
- c. Donor NAT (when applicable/available)
- d. HLA + Crossmatch (when applicable/ available)
- e. EDR Organ Data Page (organ specific)
- f. EDR Intraoperative Management page
- g. EDR DCD Flowsheet (when applicable)
- h. Donor Vessel Tracking Form
- i. Donor Vessel Documents Sticky Label
- j. TSANZ Organ Retrieval Report Form

Complete the Donor Vessel Tracking Form and TSANZ Organ Retrieval Report prior to enclosing in the pre-labelled envelope.

One copy of the documentation accompanies the organ and is retained to accompany the vessel package when later stored at the transplant hospital; (i.e. the one set of documents supports both organ and donor vessels).

A pre-labelled envelope is used to enclose all of the Donor/Organ Documentation and is addressed to the TRANSPLANT SURGEON (**Appendix 2**).

A green DONOR VESSEL DOCUMENTS STICKY LABEL (**Appendix 3**) is included inside the envelope with the documentation. It is completed by the Donation Specialist Coordinator with identifying information before being placed into the envelope. (This green sticky label will be used to place over the original envelope address in the recipient theatre once the implanting surgeon has completed checking the documentation) — see 4(ii).

The rationale for the single documentation and re-labelling of the envelope is to:

- a. reduce error in transcribing double documentation
- b. prevent loss or filing in recipient's notes
- c. ensure correct documentation accompanies correct organ/donor vessels.

The Donor/Organ Documentation envelope is then placed inside the transport container in a sealed zip-lock bag (to prevent moisture) and taped to the inside of the lid of the transport container.

4. Procedure for donor vessels in the recipient theatre

- a. At the recipient hospital, verification of the Donor Documentation with the vessel package and organ must be performed by the recipient coordinator or transplant technician or surgical theatre staff member and the implanting surgeon.
- b. AFTER the surgeon has checked the Donor/ Organ documentation, the original envelope is re-labelled with the green DONOR VESSEL DOCUMENTS STICKY LABEL.
- c. It is the responsibility of the implanting surgeon to ensure that a designated person, the recipient coordinator, transplant technician or surgical theatre staff has re-labelled the envelope to be retained with the donor vessels.

4.1. If vessel package NOT opened and donor vessels NOT USED

- i Place donor vessels in a designated refrigerator in the operating theatre complex. Donor vessels MUST be accompanied by the VESSEL DOCUMENTS ENVELOPE, (in a plastic sleeve) and stored together, ensuring they are not separated. Donor vessels should be stored in a secure designated refrigerator (temperature monitored and maintained within a range of 2–8 degrees Celsius) together with the Donor Vessel Documents envelope.
- ii It is the responsibility of the local designated staff member who places the documents with the donor vessels package for storage in the refrigerator to also document in the local Donor Vessel Log Record.

4.2. If vessel package OPENED and only ONE vessel container opened and used

- a. If the inner vessel container has been opened onto the sterile field in the operating theatre of the transplant recipient, it is considered contaminated and can ONLY be used for this recipient. Any remaining unused vessel from the 'opened' inner container must be discarded.

In some circumstances, a surgeon may request that a remaining piece of vessel which was opened on the sterile field be retained because of the nature of the case or potential future complications of that particular recipient. In this situation remaining vessel may be stored again under sterile conditions but MUST be clearly identified on the second outer container with the recipient ID label. Label should read TO BE USED FOR THIS RECIPIENT ONLY.

The recipient ID label should be placed partly on the lid and down the wall of the container as a breakable seal to ensure integrity. The outer container and plastic bag should also be marked with —TO BE USED FOR THIS RECIPIENT ONLY and the ID label of the transplant recipient placed on the outer plastic bag containing the vessel and documents. This is also recorded on the Donor Vessel Tracking Form (**Appendix 4**) and in the Donor Vessel Log Book.

- b. The unopened vessel container, NOT opened on the sterile field of the recipient (either artery or vein), may be stored in a separate plastic bag in the refrigerator with the donor vessels Documentation following the steps of 4.1 (i) and (ii).

Note: Donor vessels that are stored in two containers, i.e. small one inside the larger one, are considered sterile only on the INSIDE of the larger container.

Note: If a donor organ has been removed and subsequently not transplanted and the donor family have indicated they wish unused organs to be returned to the body, then the donor vessels should accompany the organ for this purpose. The DonateLife Agency or NZDS must be notified in order to return both organ and donor vessels to the deceased.

5. Procedure for storage of donor vessels at the recipient hospital

- a. Donor vessels should be stored in a secure designated refrigerator (temperature monitored and maintained within a range of 2–8 degrees Celsius) together with the Donor Vessel Documents.
- b. The donor vessels should be stored for no longer than 14 days from the original retrieval date.
- c. After 14 days from retrieval date:
 - i. the donor vessels MUST be discarded according to the local hospital disposal of human tissue policy.
 - ii. the Vessel Tracking Form (contained in the Donor Vessel Document envelope) completed with the outcome (not used/used) and faxed to the DonateLife Agency of the DONOR's state of origin. For example, Queensland donor, Victorian recipient: fax form back to DonateLife Queensland Agency, NOT DonateLife Victoria.
 - iii. fax numbers are provided on the bottom of the tracking form.
- d. The remaining documents in the envelope should be either destroyed or securely stored as confidential documents as per Transplant Unit procedure (advised by local Transplant Unit).

6. Procedure for positive serology cases

If donor vessels have been procured from a seropositive donor (positive for HIV, Hepatitis B, or Hepatitis C) for a designated transplant recipient, donor vessels should NOT BE STORED after the completion of the transplant operation.

The *TSANZ Clinical Guidelines for Organ Transplantation from Deceased Donors* permits the use of seropositive donors for seropositive recipients and in some situations where the recipient is not seropositive where the treatment will not harm the recipient (e.g. Hepatitis B Core positive liver donor into a naïve recipient). However, International Guidelines¹ recommend the discontinuation of storage of donor vessels from donors that are seropositive or nucleic acid positive, even if their storage was designated for use only with the original organ. This practice would remove the potential for human error, which may result in inadvertent use in a seronegative recipient. Furthermore, no problems related to vessel availability have been noted since this practice has occurred overseas.

7. Use of donor vessels for patients other than the intended organ recipient

There are rare circumstances when vessels procured from a deceased donor might be considered for use in a patient other than the patient who was transplanted with the organ of that donor. For example, an organ recipient may present in a delayed fashion with a vascular complication beyond the period of time that their donor's vessels have been stored. This can be a graft- and/or life-threatening problem that could be potentially solved by using a vascular graft from a blood group compatible subsequent donor. In this situation, it is the responsibility of the surgeon to:

- a. determine the appropriateness of using the graft
- b. assess the relative risks and benefits of using this and other graft types
- c. check the documentation accompanying the donor vessels, particularly with regard to serology and identified risks
- d. check the electronic donor record to assess the risks associated with the donor, including past medical history, social history and serology
- e. obtain informed consent from the patient, particularly with regard to the risks associated with the use of donor vessels as grafts and taking into account specific risks identified in the donor of the blood vessels to be used, notify the local DonateLife agency of the donor and patient details so that subsequent patient tracking can be undertaken.
- f. Notify the local DonateLife Agency of the donor and patient details so that subsequent patient tracking can be undertaken.

1

¹ Extracted from Potential Transmission of Viral Hepatitis through Use of Stored Blood Vessels as Conduits in Organ Transplantation— Pennsylvania, 2009, February 18, 2011 / 60(06); 172–174 *American Journal of Transplantation* 2011; 11: 863–865

VII. Version Control

| | |
|-----------------|----------|
| SOP Reference | 003/2016 |
| Current Version | 2.0 |
| Review date | Ongoing |

| Version # | Changes | Release Date |
|-----------|--|---------------|
| 2.0 | Deleted 7.v on page 7: "Check in the electronic data record that consent has been given by the donor family for use of vessels in patients other than the solid organ recipients in an emergency setting" Deleted the words "if necessary" in 7.vii on page 7 | December 2016 |

Appendix 1


VESSELS

| | | | |
|--------------|-----------|--------------|-----------|
| Donor Number | Donor MRN | Donor D.O.B. | Donor ABO |
|--------------|-----------|--------------|-----------|

Organ labelled by:

.....

Full Name and Signature




The logo for 'donatelife' features the text 'donatelife' in a sans-serif font above a circular graphic. The graphic consists of three black arrows forming a clockwise cycle around a central white heart shape.

Appendix 2

Donor / Organ Documentation

Confidential Information for Transplant Surgeon



Donor No: _____

Donor State: _____

Organ: _____


Retrieval Date: _____

Retrieval Coordinator: _____

Contact No: _____


This envelope contains:

| | |
|-------------------------------------|--------------------------|
| Donor blood group | <input type="checkbox"/> |
| Donor serology | <input type="checkbox"/> |
| Donor NAT | <input type="checkbox"/> |
| HLA + Crossmatch | <input type="checkbox"/> |
| EDR Organ Data Page | <input type="checkbox"/> |
| EDR Intraoperative Management page | <input type="checkbox"/> |
| EDR DCD Flowsheet | <input type="checkbox"/> |
| Donor Vessel Tracking Form | <input type="checkbox"/> |
| Donor Vessel Documents Sticky Label | <input type="checkbox"/> |
| TSANZ Organ Retrieval Report Form | <input type="checkbox"/> |



IF THERE ARE NO VESSELS ACCOMPANYING THIS ORGAN, RETURN THIS ENVELOPE AND CONTENTS TO YOUR HOSPITAL TRANSPLANT/DONOR COORDINATOR OR SHRED

DO NOT FILE THESE DOCUMENTS IN THE RECIPIENT RECORD


T · S · A · N · Z

Appendix 3

Donor Vessel Documents



Donor No: _____ Donor State: _____

Retrieval Coordinator: _____ Phone No: _____

Retrieval Date: _____

1. Place this sticker on the front of the Donor / Organ Information and Documentation envelope

2. This envelope with the accompanying documents **MUST** be stored at all times with the vessels in the designated refrigerator

3. **AFTER 14 DAYS**, when vessels have been used or discarded, fax the enclosed “Donor Vessel Tracking Form” to the donor state agency and shred the envelope with remaining documents

This envelope contains:

- Donor blood group
- Donor serology
- Donor NAT
- HLA + Crossmatch
- EDR Organ Data Page
- EDR Intraoperative Management page
- EDR DCD Flowsheet
- Donor Vessel Tracking Form

Appendix 4

Donor vessel tracking form






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| Donor identification details | | Serology (please tick) | | |
|---------------------------------|--------------------------------------|------------------------|---------------------|-----------------|
| | | Non Reactive | Reactive | Not Done |
| Retrieval Coordinator | | HIV 1 / 2 | | |
| Contact number | | Hep B Surf Ag | | |
| Donor State Agency | Fax No: | Hep B Surf Ab | | |
| | | Hep B Core Ab | | |
| Donor Number | State | Hep C | | |
| | | HTLV 1 / 2 | | |
| Donor ABO | Donor DOB Donor UR | Syphilis | | |
| | | CMV | | |
| Artery <input type="checkbox"/> | Vein <input type="checkbox"/> Other: | EBV | | |
| | | Toxoplasmosis | | |
| Date and X-Clamp Time | ___ / ___ / ___ ____ hrs | NAT / PCR | Not Detected | Detected |
| | | HIV | | Not Done |
| Date to be discarded | (14 days post retrieval) | Hep C | | |
| | | Hep B | | |

If vessels NOT USED after 14 days:

1. Discard vessels as per hospital protocols
2. Fax Donor Vessel Documentation form to the donor state DonateLife Agency

| Faxed by: | Print Name & Designation | Contact phone | Date |
|-----------|--------------------------|---------------|------|
| | | | |

Surgeon to complete if VESSELS USED:

1. Affix patient identification label in the space provided and complete details
2. Fax Donor Vessel Tracking form to the donor state DonateLife Agency
3. File Donor Vessel Tracking form in the vessel recipients hospital notes

| <ol style="list-style-type: none"> 1. Date vessels were used: _____ 2. Which vessels used: _____ 3. Any unused vessels discarded? _____ 4. Name of Surgeon: _____ 5. Hospital and State: _____ | <div style="border: 1px solid black; padding: 10px; width: 80%; margin: auto;"> <p style="margin: 0;">Affix patient identification label of Recipient of vessels</p> </div> | | | | | | | | |
|--|---|---------------|--------------------------|---------------|------|--|--|--|--|
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #1a3d4d; color: white;"> <th style="width: 15%;">Faxed by:</th> <th style="width: 45%;">Print Name & Designation</th> <th style="width: 20%;">Contact phone</th> <th style="width: 20%;">Date</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> | | Faxed by: | Print Name & Designation | Contact phone | Date | | | | |
| Faxed by: | Print Name & Designation | Contact phone | Date | | | | | | |
| | | | | | | | | | |

DonateLife Agency fax numbers

| | | | |
|------------------|-----------------|----------------------|------------------|
| QLD 07 3176 2999 | WA 08 9222 0220 | NSW 02 8566 1755 | VIC 03 9349 2730 |
| SA 08 8207 7102 | NT 08 8944 8096 | NZ 0011 64 9623 6490 | |