National Standard Operating Procedures

Packaging, labelling, storage and
Documentation of deceased donor vessels

Version 1.0 ATCA-TSANZ SOP 003/2013
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Version Control

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Author Tina Coco
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• TSANZ Council
• ATCA Committee
• Organ and Tissue Authority (OTA)
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Terminology

**Donor vessels:** are arteries and veins retrieved in the organ donation surgery for the purposes of extension grafts and/or for vascular reconstruction as part of transplant surgery. Donor vessels include any arteries or veins which are accessible. The donor vessels most routinely retrieved are:

- the common, external and internal iliac arteries and veins
- superior mesenteric artery and vein
- internal jugular vein
- carotid artery
- subclavian veins.

**Vessel Package:** refers to the sterile container that holds either the arteries or veins, stored together in one package (plastic bag). The vessel package accompanies the organ for transplantation.

**Transport container:** refers to the hard shelled container which stores the organ and donor vessels for transport to the transplant hospital.

**Retrieval coordinator:** refers to the person responsible for the labelling, packaging and documentation of organs and donor vessels in the donor theatre. The role of this person varies between jurisdictions and may be either the Donation Specialist Coordinator; the perfusionist (who is a member of the abdominal retrieval team) or a recipient coordinator (who is a member of the cardio-thoracic team).

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.

Purpose

This Standard Operating Procedure (SOP) 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.

Scope

This SOP applies to donor vessels retrieved in the deceased organ donor setting. This SOP is benchmarked against international practice and safety guidelines, namely United Network for Organ Sharing UNOS Policy and the Centres for Disease Control and Prevention.

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

- 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.

- Heads of transplant units, the Organ and Tissue Authority (OTA) through the DonateLife State and Territory Medical Directors, Managers of DonateLife Agencies and Organ Donation New Zealand (ODNZ) have the responsibility for ensuring that relevant staff under their supervision utilise this SOP.

- 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 DonateLife Agency or ODNZ of outcomes by return fax.

- It is the responsibility of each DonateLife Agency and ODNZ to commence the TSANZ/ATCA Donor Vessel Tracking Form and ensure it accompanies the donor organ(s) and vessel(s) to the recipient hospital.

- After 14 days, it is the responsibility of each DonateLife Agency and ODNZ to contact the recipient hospital to arrange for the completed TSANZ/ATCA Donor Vessel Tracking Form to be sent back to the DonateLife Agency home state/territory to be filed. It should identify and document the use and disposal of any vessels retrieved for transplantation purposes.

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 SOP:

All jurisdictions with the exception of NT and SA 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’.
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.

1.1 Surgical process

a. The scrub nurse (on the sterile field) records the donor identification information (provided by the Donation Specialist Coordinator) on the provided sterile label of the inner containers using a Codman® pen and then covers the label with an Opsite® to prevent ink run (Appendix 1).

b. The donor surgeon places each donor vessel separately in each of the two inner containers. The inner container must be a sterile rigid container (eg.120ml specimen jar with lid).

c. The scrub nurse with the aid of the retrieval coordinator uses the perfusion giving set to half fill each inner container with the perfusion solution. Vessels should be packaged in the same way as organs (as prescribed by the TSANZ Consensus Statement on Eligibility Criteria and Allocation Protocols for the handling of organs) ie. triple-bagged and with the appropriate accompanying documentation.

d. The scrub nurse places the first rigid labelled container inside the second rigid container, seals it, then hands each vessel to the retrieval coordinator. The second packaging must be a larger sterile rigid container (eg. 250ml specimen jar with lid), allowing the air between the two to act as an insulator in order to reduce the risk of vessels freezing.

e. The retrieval coordinator records the same donor identifying information on the larger outer rigid containers.
The information recorded on both containers includes the retrieval date, donor blood group, Donor Number, hospital UR number, type of vessel, i.e. artery or vein, which is provided by the Donation Specialist Coordinator.

The retrieval coordinator places the vessel package containers into one plastic bag and ties it off with a vessel ID tag (Appendix 2).

Arteries and veins should be placed in separate containers but always stored together in one plastic bag together with the documentation. The plastic bag with the donor vessels (one artery and one vein) 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 outer packaging should be a plastic bag, for example, a bowel bag (this does not need to be sterile) to keep both artery and vein containers together.

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

Note: Flow sheet outlining surgical retrieval and labelling of donor vessels are the responsibilities of the scrub nurse and retrieval coordinator and can be used as a guide for staff (Appendix 6).
2. Documentation to accompany donor vessels for transport

a. At the donor hospital when the donor vessels are labelled and packaged for transport, verification of the Donor Number and Donor/Organ Documentation to accompany the organ and the donor vessels must be performed by the retrieval coordinator and a member of the surgical retrieval team.

b. The donor/organ documentation that accompanies the organ and donor vessels is:
   1. Donor blood group
   2. Donor serology
   3. Donor NAT (when applicable/available)
   4. HLA + Crossmatch (when applicable/available)
   5. EDR Organ Data Page (organ specific)
   6. EDR Intraoperative Management page
   7. EDR DCD Flowsheet (when applicable)
   8. Donor Vessel Tracking Form
   9. Donor Vessel Documents Sticky Label
   10. TSANZ Organ Retrieval Report Form

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

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

e. A pre-labelled envelope is used to enclose all of the Donor/Organ Documentation and is addressed to the TRANSPLANT SURGEON (Appendix 3).

f. A green DONOR VESSEL DOCUMENTS STICKY LABEL (Appendix 4), 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 3(b).

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

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

g. 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.
3. 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.

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

a. 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.

b. 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.

3.2. 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 5) 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 3.1 (a) and (b).

NOTE: Donor vessels that are stored in two containers, ie. 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 ODNZ must be notified in order to return both organ and donor vessels to the deceased.

Flow sheet relating to process in the recipient theatre can be used as a guide for staff (Appendix 7).

4. 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:

   - the donor vessels MUST be discarded according to the local hospital disposal of human tissue policy
   - 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
   - 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).
5. 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 Consensus Statement on Eligibility Criteria and Allocation Protocols 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 (eg. Hepatitis B Core positive liver donor into a naïve recipient). However, International Guidelines\(^1\) 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.

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## Appendix 1

Artery and vein labels (sterile for scrub nurse)

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<td>MRN:</td>
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Appendix 2

Vessel ID tag

VESSELS

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

Organ labelled by:

Full Name and Signature
Appendix 3

Donor/organ Information and documentation envelope

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
- Donor serology
- Donor NAT
- HLA + Crossmatch
- EDR Organ Data Page
- EDR Intraoperative Management page
- EDR DCD Flowsheet
- Donor Vessel Tracking Form
- Donor Vessel Documents Sticky Label
- TSANZ Organ Retrieval Report Form

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.
Appendix 4

Donor vessels documents sticky label (for envelope)

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 5

Donor vessel tracking form

<table>
<thead>
<tr>
<th>Donor identification details</th>
<th>Serology (please tick)</th>
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<tbody>
<tr>
<td>Retrieval Coordinator</td>
<td>HIV 1 / 2</td>
</tr>
<tr>
<td></td>
<td>Hep B Surf Ag</td>
</tr>
<tr>
<td>Contact number</td>
<td></td>
</tr>
<tr>
<td>Donor State Agency</td>
<td>Hep B Surf Ab</td>
</tr>
<tr>
<td></td>
<td>Hep B Core Ab</td>
</tr>
<tr>
<td>Fax No:</td>
<td></td>
</tr>
<tr>
<td>Donor Number</td>
<td>Hep C</td>
</tr>
<tr>
<td></td>
<td>HTLV 1 / 2</td>
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<tr>
<td>Donor ABO</td>
<td>Syphilis</td>
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<td>Donor DOB</td>
<td>CMV</td>
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<tr>
<td>Donor UR</td>
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<tr>
<td>Artery</td>
<td>EBV</td>
</tr>
<tr>
<td>Vein</td>
<td>Toxoplasmosis</td>
</tr>
<tr>
<td>Other:</td>
<td></td>
</tr>
<tr>
<td>Date and X-Clamp Time</td>
<td>HIV</td>
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<td></td>
<td></td>
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<td></td>
<td>Date to be discarded</td>
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<td>(14 days post retrieval)</td>
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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

<table>
<thead>
<tr>
<th>Fax by:</th>
<th>Print Name &amp; Designation</th>
<th>Contact phone</th>
<th>Date</th>
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</table>

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

<table>
<thead>
<tr>
<th>Fax by:</th>
<th>Print Name &amp; Designation</th>
<th>Contact phone</th>
<th>Date</th>
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**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

Affix patient identification label of Recipient of vessels
Appendix 6

Donor vessel flow chart for donor theatre (for training purposes)

Responsibilities of the scrub nurse

The Scrub Nurse will be provided with:
1. Small sterile specimen jars with lids (eg 120 mls)
2. Large sterile specimen jars with lids (eg 250 mls)
3. Sterile vessel labels: Artery and Vein
4. Sterile Codman pen
5. Opsite (small)

The Scrub Nurse will:
1. Complete vessel labels with the required donor information provided by the Donor/Retrieval Coordinator
2. Scrub nurse to place completed sterile vessel labels on small specimen jars and place Opsite over label (to prevent ink running)
3. Half fill each small sterile specimen jar with perfusion solution
4. Surgeon will place donor ARTERY in the prepared small specimen jar
5. Surgeon will place donor VEIN in the prepared small specimen jar
6. Place small labelled jar into large sterile specimen jar and seal with the lids
7. Hand off both sealed containers to the Donor/Retrieval Coordinator

Responsibilities of the retrieval coordinator

The Donor/Retrieval Coordinator will:
1. Complete unsterile artery and vein vessel labels and place on both large containers
2. Complete vessel ID tag with the required donor information
3. Place BOTH the artery and vein containers into one plastic bag and tie off with a vessel ID tag
4. Place bagged vessels into the ice in the transport container with the relevant organ, ensuring vessels are completely covered with ice
5. Donor documentation is placed in the Donor/Organ Documentation envelope in a sealed zip-lock bag and placed in the transport container to accompany the organ and vessels to the recipient hospital/theatre
Appendix 7

Donor vessel flow chart
for recipient theatre (for training purposes)

Standard operating procedure for documentation, use & storage of donor vessels
Process in the transplant hospital recipient theatre

Verification of donor documentation
1. All donor documentation is contained in the sealed envelope in the transport container with the organ and vessels
2. Verification of donor documentation is performed by transplanting surgeon and either recipient coordinator, transplant technician or theatre staff member

Vessels opened and used
- Vessel containers opened onto sterile field considered CONTAMINATED
- Remaining UNUSED vessels are to be DISCARDED at end of recipient transplant surgery

Surgeon request to retain vessels for current recipient
1. Vessels in small container placed inside large container in a sterile manner
2. Place recipient ID label/sticker over the lid and down side of outer container to seal
3. Place container in clear plastic bag and place recipient ID label/sticker on outside of plastic bag
4. Clearly mark bag with: TO BE USED FOR THIS RECIPIENT ONLY and adhere recipient ID label
5. Document vessel usage on the Donor Vessel Tracking Form
6. Place plastic bag with vessels and documents in designated refrigerator
7. Document storage of vessels in the Donor Vessel Log Book

Storage of donor vessels at the transplant recipient hospital
1. Vessels should be stored in a designated refrigerator which is temperature monitored and maintained within a range of 2-8 degrees Celsius
2. Vessels should NOT be stored for longer than 14 days from the original retrieval date
3. After 14 days of storage:
   a. vessels MUST be discarded
   b. Vessel Tracking Form completed and faxed to the DonateLife Donation Agency of the Donor’s state of origin
   c. Remaining vessel donor documents should be destroyed or securely stored as confidential information as per Transplant Unit policy

Vessels not opened or used
1. Place the DONOR VESSEL DOCUMENTS envelope inside the plastic bag containing the donor vessel containers and resell
2. Place plastic bag with vessels and documents in designated refrigerator
3. Document storage of vessels in the Donor Vessel Log Book