National Standard Operating Procedures

Packaging, Labelling, Storage and Documentation of Deceased Donor Vessels

Version 5.0 ATCA-TSANZ SOP April 2020

Australian Government
Organ and Tissue Authority

donate life

TSANZ
The Transplantation Society of Australia and New Zealand

ATCA

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I. Background

The use of donor vessels retrieved in the deceased organ donor setting forms part of the standard practice for solid organ transplantation, particularly within the abdomen. Donor vessels are used to facilitate the transplantation of liver, pancreas, intestinal and renal allografts. The donors vessels most routinely retrieved are:

- The common, external and iliac arteries and veins
- Superior mesenteric artery and vein
- Internal jugular
- Carotid artery
- Subclavian veins

II. Purpose

This protocol outlines the procedures and 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 from deceased organ donors.

This protocol does not apply to whole organs retrieved for tissue donation (i.e. whole heart and accompanying vessels retrieved for cardiovascular tissue), nor does it apply to any other human tissues such as corneas, musculo-skeletal tissue or skin.

IV. Responsibility

The responsibility for review of this document lies with the Transplantation Society of Australia and New Zealand (TSANZ) and Donor Surgeons, 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 Standard Operating Procedure (PROTOCOL).

The transplant centre is responsible for the; storage of donor vessels; maintaining the appropriate Donor Vessel Log Record; discarding of unused donor vessels; completing the Donor Vessel Tracking Form (DVTF) and notifying the DonateLife Agency or Organ Donation New Zealand (ODNZ) of outcomes by return email or fax.

It is the responsibility of each DonateLife Agency or ODNZ to:

I. commence the TSANZ/ATCA *Donor Vessel Tracking Form* and ensure it accompanies the donor organ(s) and vessel(s) to the recipient hospital.

II. enter information regarding the retrieval of vessels in to the Electronic Donor Record (EDR), organ disposition pages (Australia only)

III. enter information regarding the retrieval of vessels in to the ODNZ Donor Database (New Zealand only)

It is the responsibility of the transplant unit to ensure the ***Donor Vessel Tracking Form*** is returned after 14 days and any remaining tissues disposed of. The form should identify and document the use and disposal of any vessels retrieved for transplantation purposes. Outcomes of vessels are to be documented in the EDR organ disposition pages (Australia only) or the ODNZ Donor Database (New Zealand only).

It is the responsibility of all retrieval coordinators to perform the functions outlined above according to individual state practice.

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 differences between jurisdictions when applying this protocol.

VI. Processes, Procedures and Documentation

1. Retrieval of donor vessels

It is routine for donor vessels (arteries and veins) to be retrieved for liver, whole pancreas and intestinal transplantation. Vessels may also be retrieved for renal transplantation.

If the liver is split, artery(s) and vein(s) 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 – packaging and labelling of donor vessels

Arteries and veins are placed in containers with preservation solution and are triple packaged similarly to solid organs.

The smaller inner container:

- is inclusive of the vessel(s) and perfusion solution
- must be a sterile container
- once sealed, inner container is placed within a larger container

The larger container:

- is inclusive of the smaller inner container
- must be a sterile container
- once sealed, the second layer must be placed within the third and outer packaging

Cold slush is recommended within the second (larger) container.

The two inner containers are each to be labelled with vein and/or artery as well as the three donor identifiers:

Donor ID, MRN and DOB.

The third and outer packaging/bag does not need to be sterile and is labelled with the ***Vessel ID tag*** (Appendix 1). The ***Vessel ID tag*** must be ticked to indicate those vessels included within the package.

The decision to package the artery and vein together or separately in the first container, is at the discretion of the retrieval surgeon unless requested by the implanting surgeon.

NB: If the artery and vein are packaged separately in the first instance (separate first and second layer containers used), they can then be stored together in the third outer layer.

The vessels must NOT be contained within the sterile layers of the organ packaging.

Both vessels and the associated organ can be placed together within the same transport container, ensuring that both packages are completely surrounded and covered by ice.

In NZ, the vessel packages may be placed in a separate transport container for logistical reasons

3. Documentation to accompany donor vessels for transport

Two separate envelopes are required:

1. *Donor/Organ Documentation* envelope **(Appendix 2)** and
2. *Donor Vessel Documentation* envelope **(Appendix 3)**

Indicate the following in the tick boxes provided:

- "Tick" if document enclosed in envelope
- Place the letter "T" if documents have been electronically transmitted

Both envelopes are to be placed inside the transport container in a sealed zip-lock bag (to prevent moisture).

The documentation enclosed in the ***Donor/Organ Documentation*** envelope that accompanies the organ includes de-identified copies of:

- Donor blood group
- Donor serology
- Donor NAT (when applicable/available)
- HLA + Crossmatch (when applicable/ available)
- TSANZ Organ Retrieval Report Form
- Organ Data Page (ODNZ only)

With the following documents transmitted post operatively

- EDR Organ Data Page (organ specific) – transmitted (Australian donors only)
- EDR Intraoperative Management page – transmitted (Australian donors only)
- EDR DCD Flowsheet (when applicable) – transmitted (Australian donors only)

The documentation enclosed in the ***Donor Vessel Documentation*** envelope that accompanies the vessels includes de-identified copies of:

- Donor blood group
- Donor serology
- Donor NAT (when applicable/available)
- *Donor Vessel Tracking Form*

These documents then accompany the vessel package when later stored at the transplant hospital

4. Procedure for donor vessels in the recipient theatre

At the recipient hospital, the recipient coordinator/transplant technician/surgical theatre staff member AND the implanting surgeon must verify the ***Donor/Organ Documentation*** that has accompanied the organ.

It is the responsibility of the implanting surgeon to ensure that a designated person; the recipient coordinator, transplant technician or surgical theatre staff has reviewed the ***Donor Vessel Documentation*** envelope and ensure it is 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 ID tag*** and ***Donor Vessel Documentation*** envelope (in a plastic sleeve), and stored together, ensuring they are not separated.

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 the vessel package is OPENED and only ONE vessel is used

i. If the inner container (repository for the vessels) 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.

However, 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 for future complications of that particular recipient. In this situation the remaining vessel may be stored again under sterile conditions but MUST be clearly identified on the second AND third layer with the recipient ID label. Both labels (second and third layer) must 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 second container as a breakable seal to ensure integrity. Once transplanted or discarded at a later date, this is also recorded on the ***Donor Vessel Tracking Form*** (**Appendix 4**) and in the Donor Vessel Log Book.

ii. Unopened vessel containers, NOT opened on the sterile field of the recipient (either artery or vein), must be stored in the designated refrigerator. These vessels must remain triple packaged with the donor vessels documentation and labelled with the ***Vessel ID tag***. Ensure the ***Vessel ID tag*** is labelled accordingly to indicate remaining vessel(s) (artery and/or vein).

Note: If a donor organ has been removed and subsequently not transplanted and the donor family have indicated on the consent form that unused organs are 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.

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

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 Documentation.

The donor vessels should be stored for no longer than 14 days from the original retrieval date.

After 14 days from retrieval date:

- the donor vessels MUST be discarded according to the local hospital disposal of human tissue policy.
- the ***Donor Vessel Tracking Form*** must be completed with the outcome (discarded/transplanted) and faxed or emailed to the DonateLife Agency or ODNZ of the DONOR's state of origin.

The remaining documents in the envelope should be either destroyed or securely stored as confidential documents as per recipient Transplant Unit procedure (advised by local Transplant Unit).

6. Procedure for positive serology cases

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

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

There are rare circumstances when vessels retrieved 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 deceased donor vessels 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 EDR or ODNZ referral to assess the risks associated with the donor, including past medical history, social history and serology

e. obtain informed consent from the recipient (where possible, otherwise as soon as practicable), particularly with regard to the risks associated with the use of donor vessels and taking into account specific risks identified in the vessel donor.

f. complete the ***Donor Vessel Tracking Form*** and returned to the DonateLife Agency or ODNZ of the donor's state of origin

VII. Version Control

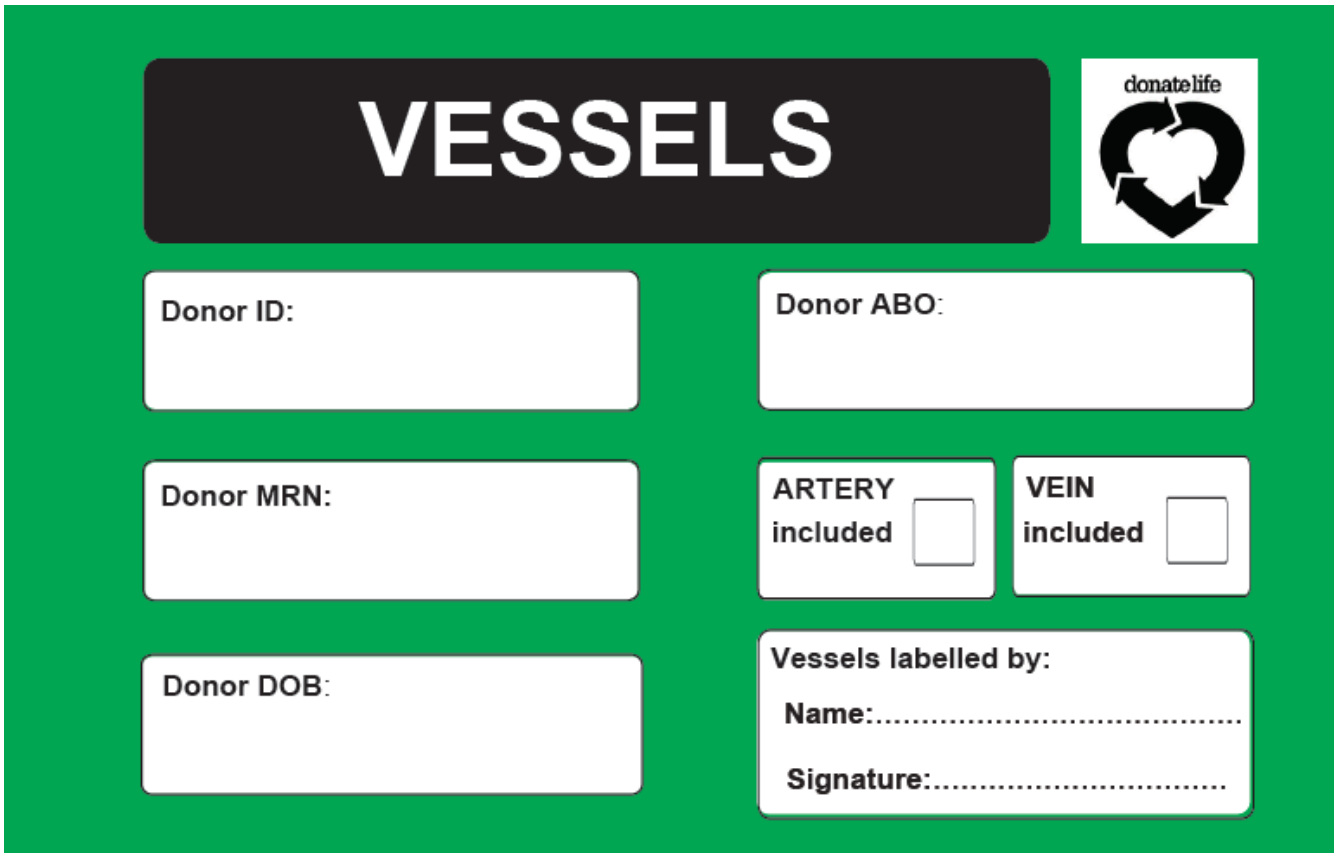
SOP Reference	ATCA-TSANZ SOP 003/2016
Current Version	Version 5.0
Review date	January 2023

Change No.	Previous document	Current document
1	New Zealand Donation Service- NZDS	Terminology changed to Organ Donation New Zealand – ODNZ throughout document
2	Donor vessels documents envelope	Name changed to "donor vessel documentation envelope" throughout document
3	Section 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	Content reworded: • The use of donor vessels retrieved in the deceased multi-organ donor setting forms part of the standard practice for solid organ transplantation • Mention of intestinal allografts now included Content added regarding most routinely retrieved donor vessels.
4	Section II: Purpose	Paragraph gap removed
5	Section III: Scope • The protocol does not apply to any other human tissues involved in transplantation such as corneas, musculo-skeletal tissue, heart valves and skin.	Content reworded: • This protocol does not apply to whole organs retrieved for tissue donation (i.e. whole heart and accompanying vessels retrieved for cardiovascular tissue), nor does it apply to any other human tissues such as corneas, musculo-skeletal tissue or skin.
6	Section IV: Part 3. Surgical process- packaging and labelling of donor vessels	Format simplified Detail added to include two options for the first level of packaging: "The decision to package the artery and vein together or separately in the first container is at the discretion of the retrieval surgeon unless otherwise requested by the implanting surgeon.
7	Section V: Consent for donor vessel retrieval and use	Content updated highlighting the difference in state practises.
8	Section VI Part 1. Retrieval packaging and labelling of donor vessels • …. whole pancreas transplantation and intestinal transplantation	Heading reworded • Retrieval of donor vessels Content reworded: • … whole pancreas and intestinal transplantation
9	Section VI Part 2. Surgical process	Heading reworded • Surgical process- packaging and labelling of donor

		vessels Content updated to describe the type of containers that should be used and the labelling requirements of containers.
10	Section VI Part 3. Documentation to accompany donor vessels for transport	Format simplified and content updated including rational for change of practice from the use and relabeling of one envelope to the use of two separate envelopes: • Donor/Organ Documentation and • Donor Vessel Documentation
11	Section VI Part 4. Procedure for donor vessels in the recipient theatre	Format simplified and content removed regarding the previous process of relabeling of the Donor/Organ Documentation envelope
12	Section VI Part 4.2 If vessel package OPENED and only ONE vessel container opened and used	Heading changed to: If the vessel package is OPENED and only ONE vessel is used Content changed to: Label **must** read TO BE USED FOR THIS RECIPEINT ONLY 4.2 b- content now explains labelling of the unopened vessels with the vessel ID tag
13	Section VI Part 5: Procedure for storage of donor vessels at the recipient hospital	Example removed from section c ii Section iii removed regarding fax numbers
14	Section VI Part 6: Procedure for positive serology cases	Second paragraph removed as top paragraph deemed to be a sufficient explanation
15	Section VI Part 7: Use of donor vessels for patients other than the intended organ recipient Sub-category 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.	Content reworded to: • obtain informed consent from the recipient (where possible, otherwise as soon as practicable), particularly with regard to the risks associated with the use of donor vessels and taking into account specific risks identified in the vessel donor.
16	Appendix 2	Sticker updated to latest version
17	Appendix 3	Sticker updated to latest version
18	Appendix 4	DVTF updated to latest version
19		Appendix 5 added titled Donor Vessel Flowsheet

VIII. Appendices

Appendix 1 – Vessel Tag



Donor / Organ Documentation
Confidential Information for Transplant Surgeon

donatelife

Donor No: _____

Donor State: _____

Organ: _____

Retrieval Date: _____

Retrieval Coordinator: _____

Contact No: _____

☑ Contained within the envelope
T Transmitted electronically

Donor Blood Group	☐
Donor Serology	☐
Donor NAT	☐
HLA + Crossmatch	☐
EDR Organ Data Page	☐
EDR Intraoperative Management Page	☐
EDR DCD Flowsheet	☐
TSANZ Organ Retrieval Report Form	☐

February 2020

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THIS ENVELOPE AND ITS CONTENTS ARE TO BE RETURNED TO THE HOSPITAL TRANSPLANT/ DONOR COORDINATOR.

DO NOT FILE THESE DOCUMENTS IN THE RECIPIENT RECORD

T·S·A·N·Z

Donor Vessel Documentation

Donor No: _____ Donor MRN: _____ Donor DOB: _____

Retrieval Coordinator: _____ Phone No: _____

Retrieval Date: _____ Donor state:

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

2. **AFTER 14 DAYS**, when vessels have been used or discarded, fax/email the enclosed "Donor Vessel Tracking Form" to the donor state agency and shred the envelope with remaining documentation

Feb 2020

☑ **Contained within the envelope**

T **Transmitted electronically**

Donor Blood Group	☐
Donor Serology	☐
Donor NAT	☐
Donor Vessel Tracking Form	☐

Date donor vessels are to be discarded if not used:.....

Donor vessel tracking form

Donor Identification Details						
Retrieval Coordinator - Name:			Contact Number:			
State Agency:			Donor ABO:			
Donor No:		Donor DOB:		Donor MRN:		
Artery ☐		Vein ☐		Other:		
DBD X-Clamp Date: ____/____/____			DCD Date of Death: ____/____/____			
Vessels retrieved from:	Abdomen ☐		Thoracic ☐		Leg ☐	
Vessels provided with:	Whole liver ☐	L Liver ☐	R Liver ☐	Pancreas ☐	Intestinal ☐	Other (Specify) ☐

IF VESSELS NOT USED AFTER 14 DAYS (Date to be discarded ____/____/____) - Discard as per hospital protocol

Transplant Team to complete

VEIN Outcome	✓	Date	ARTERY Outcome	✓	Date
Transplanted to Intended recipient			Transplanted to Intended recipient		
Transplanted to other patient – *complete section A below*			Transplanted to other patient – *complete section B below*		
Not transplanted – Research			Not transplanted – Research		
Not transplanted – Discarded			Not transplanted – Discarded		

Section A: VEIN recipient details		Section B: ARTERY recipient details	
First name		First name	
Last name		Last name	
D.O.B		D.O.B	
Patient MRN		Patient MRN	
Surgeon		Surgeon	
Hospital		Hospital	
State		State	

Emailed or faxed by:	Name and designation	Contact phone	Date

FORM TO BE RETURNED TO THE ABOVE MENTIONED STATE AGENCY:

QLD: fax: 07 3176 2999 or donor.coordinator@health.qld.gov.au	**WA:** DonateLifeOnCall@health.wa.gov.au	**NSW/ACT:** seslhd-clinicalotds@health.nsw.gov.au
SA: donatelifesa@sa.gov.au	**NT** fax: 08 8944 8096 or DLNTCoordinators.DoH@nt.gov.au	**VIC** fax: 03 9349 2730 or dlvcaseworkervic@redcrossblood.org.au
TAS: dltcaseworker@ths.tas.gov.au	**NZ:** fax: 0011 64 9 630 9907 or donornz@adhb.govt.nz	

Donor Vessel Tracking Form April 2020

Appendix 5– Donor Vessels Flowsheet