Clinical Process Instruction Manual

Perfusion & Packaging: Composite Tissue Allograft Process Instruction

Policy:

For cases where Trillium Gift of Life Network (TGLN) provides surgical recovery support, TGLN's Surgical Recovery Coordinator (SRC) or designate will facilitate perfusion and packaging of tissues, using aseptic technique and in accordance otherwise with the *Health Canada Safety of Human Cells, Tissues and Organs for Transplantation Regulations*. For recovery procedures performed by the transplant programs, the designate undertakes surgical recovery activities including perfusion and packaging.

The SRC or designate refers to the *Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406* prior to departing for recovery.

Process:

Prior to Departing TGLN

1. The SRC or designate obtains the appropriate documentation required for recovery. Forms include:
    - *Reporting Form: Clinical Services Coordinator to Surgical Recovery Coordinator*
    - *Organ Donor Surgery Information*
    - *Composite Tissue Allograft Retrieval Operative Note* (See Exhibit 1)
    - *Composite Tissue Transplant Operating Room Data* (with attached ABO and Serology). See Exhibit 2.
    - *Public Health Requisition* from Public Health (if required)
    - *Laboratory Services Requisition: STAT Infectious Disease Testing of Organ Donors* (if required)
    - Labels
    - Specimen Labels
    - Surgical supply list (if needed)

    For organ recoveries performed by transplant programs, the *Organ Donor Surgery Information* and the *Composite Tissue Transplant Operating Room Data* (if recipient was Ontario based) are sent back to TGLN's Provincial Resources Centre (PRC) for filing with the donor chart.

2. The SRC or designate prepares the composite tissue allograft surgical recovery kit (please note kits are designated by a tag for adult and paediatric donors). The SRC or designate reviews the contents of the kit to ensure that all of the following required supplies are present:
    - 2 sterile Y perfusion tubing
    - 2 portal tubing (cannula)
    - 2 vessel perfusion cannula(s)
    - 6 3M Steri-Drape Bags

- 12 CardioMed organ bags
- 4 red top tubes
- 4 EDTA tubes
- 4 ACD tubes
- 2 pour spouts
- 10 specimen bags
- 4 sterile specimen containers

3. In addition to the items listed in the kit, the SRC or designate will bring a manual pump for the replacement tourniquet.

4. The SRC or designate confirms that all sealed items have not been tampered with, equipment is sterile and all supplies are within expiration dates. The SRC or designate replaces supplies and/or equipment if there is any uncertainty regarding its integrity and places these supplies in designated area in surgical supply room.

5. The SRC or designate obtains a large cooler and places the following items within:
   - wet ice (fill 1/3 of the cooler)
   - 7 to 8L Static Preservation Solution (SPS-1) or University of Wisconsin (UW)
   - 6 to 8 L slush

6. The SRC or designate may require a small red styrofoam cooler to contain all unused supplies post-recovery that may require refrigeration.

7. The SRC or designate picks up the recovery team at predetermined time and location.

Upon Arrival at Recovery Hospital

8. The SRC or designate notifies the PRC of his/her arrival time.

9. The SRC or designate introduces the recovery team to the OR staff.

10. The SRC or designate records the names of the OR staff (if time permits) and the donor hospital's civic address and contact information (phone number) on the *Organ Donor Surgery Information.*

11. The SRC or designate reviews the patient's chart with the recovery team and confirms ABO, serology results, declarations, consent and Coroner involvement (if required). If required, the SRC or designate discusses serology results with the Organ and Tissue Donation Coordinator (OTDC) or Clinical Services Coordinator (CSC).

12. The SRC or designate records the first set of donor vitals on the *Organ Donor Surgery Information*, which includes the time, medications (RX) and dosage, blood pressure, and heart rate, if applicable. The SRC or designate records these values every applicable hour or less of the recovery process, if required.

13. The SRC or designate ensures all appropriate blood samples have been drawn and correctly labelled with TGLN identification number, donor date of birth, as well as date and time of collection. The samples are to be placed into specimen bags containing the appropriate requisitions.

14. The SRC or designate asks the OR staff for 1 intravenous (IV) pole for use during perfusion, a table, and 1 sterile basin for composite tissue allograft packaging.

15. The SRC or designate completes the surgical supply list as they remove items from the surgical supply kit. Items not appearing on the list are documented under “Other”.

16. The SRC or designate opens and passes the following sterile supplies to the scrub nurse to remain on the OR supply table:
    - Perfusion cannula
    - Portal tubing (cannula)

17. The SRC or designate scrubs in, as per aseptic protocol, and prepares the back table with the assistance of the circulating nurse. See Figure 1. The following materials are required:
    - 2 sterile basins
    - 3 3M Steri-Drape Bags
    - 8 CardioMed organ bags
    - 3 sterile specimen containers

    The SRC or designate places three 3M Steri-Drape bags over one of the sterile basins. The other sterile basin should be filled with 6L slush and sterile solution is added to create a wet slush-like consistency. The SRC or designate removes the caps from the sterile specimen containers and leaves them open on the packaging table.

Clinical Process Instruction Manual

Perfusion & Packaging: Composite Tissue Allograft Process Instruction

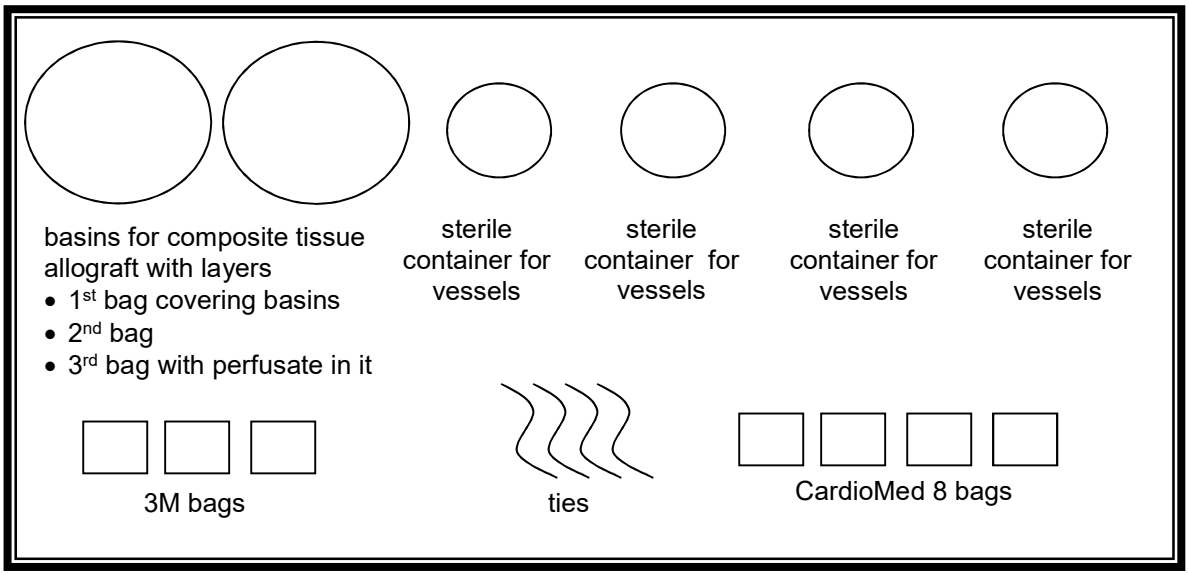

Figure 1: Sterile Back Table Set-up for Composite Tissue

18. The SRC or designate breaks scrub and opens the sterile perfusion tubing and the portal tubing to the scrub nurse. The SRC or designate will then direct the scrub nurse to attach the portal tubing to the distal end of the perfusion tubing. The portal cannula section (the skinny tubing) of the portal tubing is then removed from the portal tubing by undoing the luer lock and replaced it with the vessel cannula. The set of perfusion tubing is attached to the foot of the OR table by the scrub nurse.

19. The scrub nurse will then hand the SRC or designate the other end of the perfusion tubing set. The SRC or designate attaches perfusion line to the IV pole.

Surgical Recovery

20. Upon commencement of surgical recovery, the SRC or designate records the “skin cut time” on the *Organ Donor Surgery Information*, and notifies the CSC.

21. The SRC or designate contacts the CSC when surgeons have assessed the donor limb/face, and gives and estimated time for recovery. Accordingly, the CSC contacts the transplant physician upon notification, if applicable.

22. The SRC or designate records the time of heparin administration and the number of units administered on the *Organ Donor Surgery Information*.

23. When perfusion is imminent, the SRC or designate hangs 2 – 1L bags of SPS-1 or UW on the perfusion line near the back-table where the composite tissue perfusion will be occurring. The perfusate amounts are subject to change as per request from the surgical staff. The SRC or designate will ensure that the initial tourniquet inflate time and final tourniquet deflate time is recorded on the *Composite Tissue Transplant Operating Room Data*.

24. At perfusion, the SRC or designate records the time and opens the perfusion line. The SRC or designate will notify the surgical staff as each litre of perfusate is used and stops perfusion upon request.

25. The SRC or designate records names and volumes of perfusion and storage solution on the *Organ Donor Surgery Information.*

26. The SRC or designate notifies the CSC of perfusion time and estimated time of departure.

27. Approximately 40cc SPS-1 or UW is decanted into each of the small specimen containers for vessel/tissue transport using a pouring spout.

28. The recovered composite tissue allograft is placed in the top of the bag of the basin with 3M bags and with enough solution to immerse the graft, and then the top is tied off. Some air may be left in, as per discretion of the physician. The 2nd 3M bag is tied off. The above step is repeated with the 3rd bag.

29. The SRC or designate labels the packaged composite tissue allograft as per *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417.* The organ bag is then placed into a large cooler and onto the ice. Do not cover the packaged graft with ice.

Prior to Departing Recovery Hospital

30. A copy of the *Composite Tissue Allograft Retrieval Operative Note* is completed, signed by the appropriate surgical staff and left in the hospital donor chart.

31. Surgical staff may document any abnormalities or other comments on backside of the *Organ Donor Surgery Information*, if necessary.

32. The SRC or designate notifies the PRC and provides the aforementioned information, as well as their time of departure.

33. If unaccompanied by a member of the recovery team to the recipient OR, the SRC or designate ensures the cooler is secured with a one-time use fastener. If accompanied by a recovery team member, it is not mandatory to secure a cooler.

Clinical Process Instruction Manual

Perfusion & Packaging: Composite Tissue Allograft Process Instruction

Post Recovery

34. The SRC or designate notifies the CSC and provides a report of any abnormalities or comments previously reported, as well as their time of departure.

35. The SRC or designate ensures all lot numbers and expiry dates of all solutions and supplies used are recorded on an appropriate sheet.

36. The SRC or designate ensures that donor blood, sputum, spleen, etc. samples are dropped off at the appropriate locations as per *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*, *Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213* and *Microbiology Testing Process Instruction, CPI-9-214.*

37. The SRC or designate repacks the surgical recovery kit upon completion of organ recovery.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Surgical Supply List	CSF-9-58	PRC	PRC	16 years
Organ Donor Surgery Information	CSF-9-57	PRC	PRC	16 years
Composite Tissue Allograft Retrieval Operative Note	CSF-9-76	PRC	PRC	16 years
Composite Tissue Transplant Operating Room Data	CSF-9-75	PRC	PRC	16 years

Clinical Process Instruction Manual

Perfusion & Packaging: Composite Tissue Allograft Process Instruction

References:

- Infectious Disease Testing – STAT Process Instruction, CPI-9-211
- Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213
- Microbiology Testing Process Instruction, CPI-9-214
- Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406
- Organ and Composite Tissue Labelling Process Instruction, CPI-9-417
- Sterilization of Equipment – Organ Process Instruction, CPI-9-708
- Safety of Human Cells, Tissues and Organs for Transplantation Regulations, Health Canada, June 2007
- Health Canada Guidance Document for Cell, Tissue and Organ Establishments

Clinical Process Instruction Manual

Perfusion & Packaging: Composite Tissue Allograft Process Instruction

Exhibit 1: Vascularized Composite Tissue Retrieval Operative Note

Page 1

CSF-9-76

VASCULARIZED COMPOSITE TISSUE RETRIEVAL OPERATIVE NOTE

Hospital: _____ Date: _____

Patient Name: _____ Medical Record Number: _____

Surgeons: _____

The limb was sterilely aseptically prepped and draped in usual fashion. Previously planned skin markings applied with marking pen. A sterile tourniquet was applied. Skin incisions were made under tourniquet control and then the relevant nerves, vessels, tendons/muscles were isolated and dissected away from the bone. The nerves were transected proximal to the planned osteotomies. Once the soft tissues were retracted, the osteotomies were performed using an oscillating saw. The vessels were then transected and the limb was packaged in three layer sterile bags and packed in cooler for transport to recipient OR. The donor site was then rendered hemostatic and closed with simple sutures or staples.

Limbs procured (circle):

ADDITIONAL NOTES

Artery, veins, nerves recovered: _____

_____

Tissue recovered: _____

_____

Other: _____

_____

Signature: _____

May 12, 2021

Clinical Process Instruction Manual

Perfusion & Packaging: Composite Tissue Allograft Process Instruction

Exhibit 2: Composite Tissue Transplant Operating Room Data

Page 1

CSF-9-75

Trillium Gift of Life Network

COMPOSITE TISSUE TRANSPLANT OPERATING ROOM DATA

TRILLIUM GIFT OF LIFE
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9
Telephone (24/7): 1.877.363.8456 Facsimile: 1.866.557.6100
CTO # 100062

TRANSPLANT PROGRAMS:

TORONTO: RETURN TO ORIGINATING COOLER AND NOTIFY TGLN FOR COOLER PICK UP.
OUTSIDE TORONTO: FAX BOTH SIDES OF FORM TO TGLN @ 1-866-557-6100.
CONTACT TGLN IF YOU HAVE ANY QUESTIONS

DONOR INFORMATION **Limb: L/R** _____

DONOR TGLN #: _____ **DONOR CTD #:** _____ **RECOVERY SURGEON:** _____

DONOR AGE: ____ **DONOR ABO & Rh:** ____ **DONOR HT:** ____ cm **DONOR WT:** ____kg **DONOR CMV (P/N):** ____

NDD	**TURNIQUET ON:**	DATE: _____	TIME: _____ EST
	TURNIQUET OFF:	DATE: _____	TIME: _____ EST
	CLAMP:	DATE: _____	TIME: _____ EST
	IMMERSION:	DATE: _____	TIME: _____ EST

DONOR COMPOSITE TISSUE DESCRIPTION:

RECIPIENT INFORMATION

RECIPIENT TGLN #: _____
RECIPIENT CTR #: _____

RECIPIENT HT: _____ **cm** **RECIPIENT WT:** _____ **kg**
RECIPIENT CMV (P/N): _____ **RECIPIENT ABO & Rh:** _____
RECIPIENT PRIMARY DISEASE: _____
TRANSPLANT HOSPITAL: _____

MRN #: _____

(May use hospital sticker or stamp if available)

RECIPIENT OR: PLEASE COMPLETE THIS BOX

TRANSPLANT SURGEON: _____

TRANSPLANT START:	DATE: _____	TIME: _____EST
* **TURNIQUET ON:**	DATE: _____	TIME: _____EST
* **TURNIQUET OFF:**	DATE: _____	TIME: _____EST
* **REMOVED FROM COLD:**	DATE: _____	TIME: _____EST
* **REVASCULARIZATION:**	DATE: _____	TIME: _____EST

RN:
Please fill in these OR times. Thank you
- TGLN

January 26, 2022 Page 1 of 2

Clinical Process Instruction Manual

Perfusion & Packaging: Composite Tissue Allograft Process Instruction