Clinical Process Instruction Manual

Perfusion & Packaging: Heart-Lung 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 organs, 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. If during visual inspection of the heart or lung, one of the organs are deemed medically unsuitable, the heart or lung will be re-offered as a heart only or lung only organ to a back-up recipient.

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 obtains the appropriate documentation required for recovery. Forms include:
    - *Reporting Form: Clinical Services Coordinator to Surgical Recovery Coordinator*
    - *Organ Donor Surgery Information*
    - *Heart-Lung Retrieval Operative Note.* See Exhibit 1.
    - *Heart/Lung Transplant Operating Room Data* (with attached ABO and serology). See Exhibit 2.
    - *HLA Lab Requisition Form*
    - *Laboratory Services Requisition: STAT Infectious Disease Testing for Organ Donors* (if required)
    - *Public Health Requisition* from Public Health (if required)
    - Organ Labels
    - Specimen Labels
    - *Lung Donor Data Form* from University Health Network (UHN)
    - Surgical supply list (when needed)
    - *UHN Microbiology Requisition*

    For organ recoveries performed by transplant programs, the *Organ Donor Surgery Information* and the *Heart/Lung 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.

Note: Separate cooler sheets are required when TGH accepts an organ combination and/or cluster.

2. The SRC or designate prepares the lung surgical recovery kit. The SRC reviews the contents of the kit to ensure that all required supplies are present:
    - 2 sterile perfusion Y tubing
    - 2 tourniquet sets
    - 6 – 3M steri-drape bags
    - 2 red top tubes
    - 2 purple top tubes
    - 4 yellow top tubes(ACD)
    - 2 pour spouts
    - 3 specimen containers (non-sterile)
    - 3 – 30ml syringe slip tip
    - 10 specimen bags
    - 1 hammer (to break up slush if needed)
    - 3 sputum traps
    - 2 Thoracic Abdominal (TA) stapler (size 30)
    - 6 TA stapler refills
    - 10 venous return cannulas (sizes 12, 16,20 & 24)
    - 2 – 10cc syringes of Sodium Chloride (NaCl)
    - 4 – 21GX1.5” needles
    - 4 – 18 G x 1.5” needles
    - 4 – 10cc syringes
    - 10 microbiology requisitions
    - 1 sterile chest retractor (if not provided at the recovery facility)

3. The SRC also prepares the contents of the heart surgical recovery kit. The SRC reviews the following contents of the kit to ensure that all of the required supplies are present:
    - 2 sterile perfusion Y tubing
    - 2 tourniquet sets
    - 2 portal cannulas
    - 2 aortic root cannulas, 12G
    - 2 paediatric aortic root cannulas, 18G
    - 2 pour spouts
    - 2 pressure bags

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

5. The SRC obtains a large cooler from the TGLN surgical supply store room and places the following items within:
    - wet ice (fill 1/3 of the cooler)

- 2 – 3L Perfadex Plus
- 3 – 1L Perfadex Plus
- 4L of Servator-H or Cardioplegia for pediatric donors
- 5 bags of slush (may break up slush at TGLN or recovery facility)
- A specimen bag with the following contents:
  - 3 vials of Prostin

The SRC may require a second small red cooler to contain all unused supplies post-recovery that may require refrigeration.

- The SRC replaces depleted slush to maintain appropriate inventory of frozen slush, if required.

6. The SRC departs for the donor hospital. See *Transportation Coordination Process Instruction, CPI-9-404*.
   - The SRC picks up recovery team at predetermined time and location.

Upon Arrival at Recovery Hospital

7. The SRC notifies the PRC of his/her arrival time.

8. The SRC introduces the recovery team to the OR staff.

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

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

11. The SRC ensures all serology specimens and archival blood samples have been obtained and appropriately labelled.

12. The SRC asks OR staff for the most recent blood gas results, chest x-ray and a bronchoscope to aid the assessment of lung quality, and requests echocardiogram or angiogram to aid in assessment of heart quality.

13. The Bronchial Alveolar Lavage (BAL) sample is obtained during the bronchoscopy. The SRC must provide the sputum trap, label the container and fill out the microbiology requisition with the TGLN identification number, donor date of birth, and the date and time of specimen collection.

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14. The SRC asks the OR staff for 2 intravenous (IV) poles for use during perfusion, a table and basin for heart-lung packaging, and a 16 french foley catheter for lung retrograde flush.

15. The SRC opens the following sterile supplies to the scrub nurse to remain on the OR supply table:
    - 1 tourniquet set
    - 1 TA stapler (size 30)
    - 2 TA stapler reload
    - 1 venous return cannula (size to be determined by surgical staff)
    - 1 aortic root cannula (adult or paediatric)
    - 1 portal cannula

16. The SRC completes the surgical supply list as they remove items from the surgical supply kit.

17. The SRC scrubs in using 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
    - 1 to 2 bags of crushed slush
    - 1 – 90ml sterile specimen container

    The SRC places one bag over the sterile basin. The SRC places 2 bags of crushed slush into the bag. The SRC places the other two bags over the existing bag of ice. The circulating nurse opens the sterile syringe of NaCl and 18Gx1.5" needle to the SRC. The SRC remains sterile and draws the 1cc of Prostin into 9cc of NaCl, obtaining a 10% Prostin solution. In the sterile field the needle is switched to a 21G x 1.5" one to prevent glass chards from being re-injected into the bags. The syringe is placed onto the OR sterile supply table to be used prior to cross-clamp.

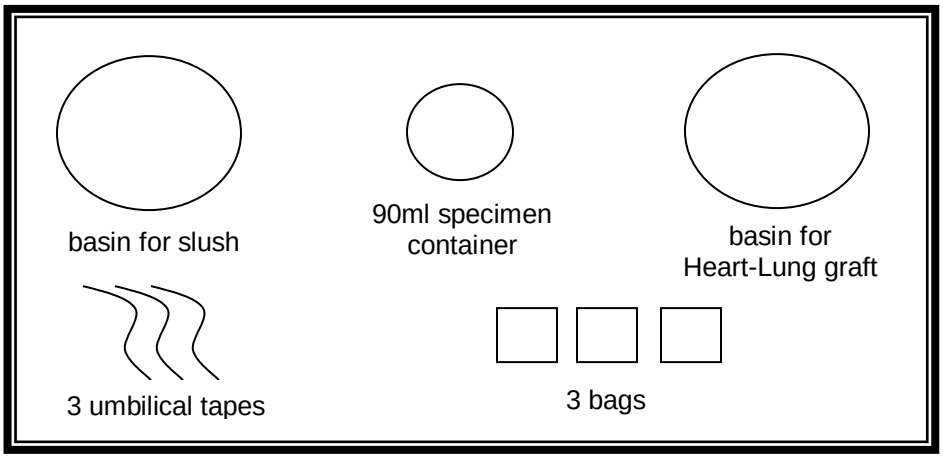

Figure 1: Sterile Back Table Set-up for Heart-Lung

Surgical Recovery

18. At commencement of surgical recovery, the SRC records the "skin cut time" on the *Organ Donor Surgery Information*.

19. The SRC notifies the PRC of skin cut time and the estimated time for aortic cross-clamp.

20. The SRC will contact the CSC when surgeons have assessed the donor heart and lungs. Accordingly, the CSC contacts the transplant physician upon notification.

21. Upon confirmation of lung quality, the SRC may prepare the Perfadex Plus bags required for perfusion.

22. Two of these bags are labelled "retrograde flush" and "packaging". The remaining 1L bag and 2.8L bag are labelled "flush" and they are further injected with:
    - 2.5cc of 10% Prostin solution per litre

23. Prior to cross-clamp, the SRC passes the sterile Y tubing to the scrub nurse. The unsterile end is passed out to the SRC and attached to an IV pole and the sterile end is secured to the head of the OR table. This procedure is repeated a second time for the lung perfusion.

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

25. When cross-clamp is imminent, the SRC hangs the Perfadex Plus bags labelled "flush" and flushes the air from the tubing with assistance from the scrub nurse or surgical team. The distal end of the tubing is secured to the head of the operating table.

26. The SRC hangs two pressure bags to the IV pole intended for heart perfusion and places two bags of Servator H or Cardioplegia inside. With the assistance of the scrub nurse, the SRC flushes the air from the perfusion Y tubing. The third bag of Servator H should remain on ice until perfusion of the first bag is complete.

27. At cross-clamp, the SRC records the time and commences perfusion of the heart and lungs. The SRC will continue to flush the remaining three bags unless otherwise directed by the thoracic team.

28. The SRC phones the CSC and provides the aforementioned information, including cross-clamp time and organ suitability. The SRC records names and volumes of perfusion and storage solutions on *Organ Donor Surgery Information.*

29. The SRC informs the appropriate surgical staff when each litre of both the Servator H and the Perfadex Plus have been emptied. Once lung perfusion is complete, the fifth bag labelled retrograde flush is attached to the Y tubing. The line is left open on the non-sterile end whilst the surgical staff clamps the distal end of tubing in order to commence use at their discretion.

30. Using a pour spout, the SRC decants the 3L storage bag of Perfadex Plus into the sterile basin on the packaging table. An additional bag of Perfadex Plus may be added to the sterile basin depending on the size of the heart-lung graft.

31. The heart-lung graft is placed in the first organ bag by the surgeon and air expressed and top of bag folded over and secured with umbilical tape.
    - The above step is repeated with the next two bags.

32. The SRC requests a splenic/lymph node sample from the surgical staff and places it in a small sterile specimen container filled with perfusate solution or normal saline. The container is appropriately labelled with the TGLN identification number, donor date of birth, contents, and the date and time of collection. The container is then placed into a specimen bag with the *HLA Lab Requisition Form*.

33. The SRC labels the packaged heart-lung graft as per *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417.* The SRC then places the organ bag into a large cooler and covers it with ice, and if unaccompanied by a member of the recovery team to the recipient OR, the SRC 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.

Prior to Departing Recovery Hospital

34. A copy of the *Heart-Lung Retrieval Operative Note* is completed and signed by the appropriate surgical staff and left in the hospital donor chart. The SRC ensures all lot numbers and expiry dates of all solutions and supplies used are recorded on the surgical supply list.

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

36. The SRC notifies the CSC and provides a report of any abnormalities or comments previously reported, as well as when they are leaving the recovery hospital.

Post Recovery

37. Upon arrival at the transplanting hospital, the SRC or designate delivers the organ to the appropriate OR staff. Prior to departure, the SRC or designate and OR staff must review all

documentation and organ label, as well as date and sign the back of the *Heart/Lung Transplant Operating Room Data.*

38. The SRC 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.*

39. The SRC repacks the surgical recovery kit upon completion of organ recovery.

40. The SRC ensures the appropriate equipment is sterilized as per *Sterilization of Equipment* – Organ *Process Instruction, CPI-9-708,* if used.

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
Heart/Lung Transplant Operating Room Data	CSF-9-54	PRC	PRC	16 years
Heart-Lung Retrieval Operative Note	CSF-9-55	PRC	PRC	16 years
HLA Lab Requisition Form	CSF-9-23	PRC	PRC	16 years

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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*
- Transportation Coordination Process Instruction, CPI-9-404
- Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406
- Organ and Composite Tissue Labelling and Re-labelling Process Instruction, CPI-9-417
- Sterilization of Equipment – Organ Process Instruction, CPI-9-708
- Health Canada. Safety of Human Cells, Tissues, and Organs for Transplantation Regulations. Canada Gazette.

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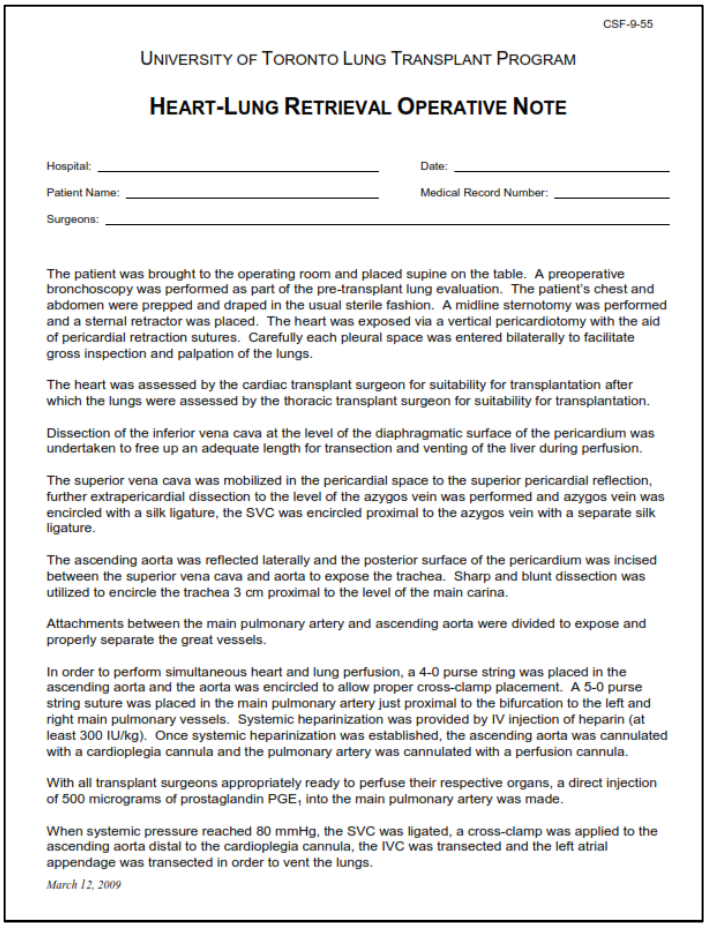
Exhibit 1: Heart-Lung Retrieval Operative Note



CSF-9-55

UNIVERSITY OF TORONTO LUNG TRANSPLANT PROGRAM

HEART-LUNG RETRIEVAL OPERATIVE NOTE

Hospital: _____ Date: _____

Patient Name: _____ Medical Record Number: _____

Surgeons: _____

The patient was brought to the operating room and placed supine on the table. A preoperative bronchoscopy was performed as part of the pre-transplant lung evaluation. The patient's chest and abdomen were prepped and draped in the usual sterile fashion. A midline sternotomy was performed and a sternal retractor was placed. The heart was exposed via a vertical pericardiotomy with the aid of pericardial retraction sutures. Carefully each pleural space was entered bilaterally to facilitate gross inspection and palpation of the lungs.

The heart was assessed by the cardiac transplant surgeon for suitability for transplantation after which the lungs were assessed by the thoracic transplant surgeon for suitability for transplantation.

Dissection of the inferior vena cava at the level of the diaphragmatic surface of the pericardium was undertaken to free up an adequate length for transection and venting of the liver during perfusion.

The superior vena cava was mobilized in the pericardial space to the superior pericardial reflection, further extrapericardial dissection to the level of the azygos vein was performed and azygos vein was encircled with a silk ligature, the SVC was encircled proximal to the azygos vein with a separate silk ligature.

The ascending aorta was reflected laterally and the posterior surface of the pericardium was incised between the superior vena cava and aorta to expose the trachea. Sharp and blunt dissection was utilized to encircle the trachea 3 cm proximal to the level of the main carina.

Attachments between the main pulmonary artery and ascending aorta were divided to expose and properly separate the great vessels.

In order to perform simultaneous heart and lung perfusion, a 4-0 purse string was placed in the ascending aorta and the aorta was encircled to allow proper cross-clamp placement. A 5-0 purse string suture was placed in the main pulmonary artery just proximal to the bifurcation to the left and right main pulmonary vessels. Systemic heparinization was provided by IV injection of heparin (at least 300 IU/kg). Once systemic heparinization was established, the ascending aorta was cannulated with a cardioplegia cannula and the pulmonary artery was cannulated with a perfusion cannula.

With all transplant surgeons appropriately ready to perfuse their respective organs, a direct injection of 500 micrograms of prostaglandin PGE_1 into the main pulmonary artery was made.

When systemic pressure reached 80 mmHg, the SVC was ligated, a cross-clamp was applied to the ascending aorta distal to the cardioplegia cannula, the IVC was transected and the left atrial appendage was transected in order to vent the lungs.

March 12, 2009

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Exhibit 2: Heart/Lung Transplant Operating Room Data

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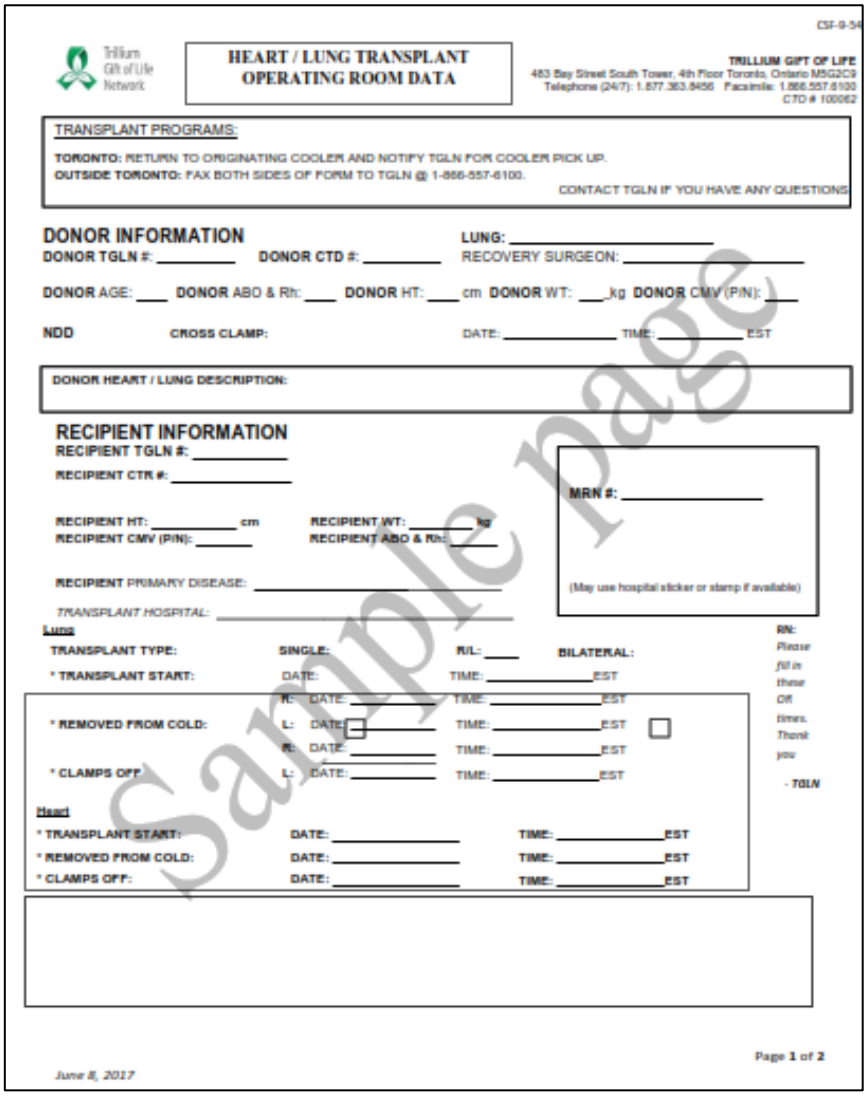

CSF-9-54

Trillium Gift of Life Network

HEART / LUNG 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
CTD # 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

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

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

NDD **CROSS CLAMP:** DATE: _____ TIME: _____ EST

DONOR HEART / LUNG DESCRIPTION:

RECIPIENT INFORMATION

RECIPIENT TGLN #: _____
RECIPIENT CTR #: _____

MRN #: _____
(May use hospital sticker or stamp if available)

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

RECIPIENT PRIMARY DISEASE: _____

TRANSPLANT HOSPITAL: _____

Lung

TRANSPLANT TYPE: **SINGLE:** R/L: ___ **BILATERAL:**

*** TRANSPLANT START:** DATE: TIME: _____ EST

*** REMOVED FROM COLD:** R: DATE: _____ TIME: _____ EST
L: DATE: _____ TIME: _____ EST

*** CLAMPS OFF** R: DATE: _____ TIME: _____ EST
L: DATE: _____ TIME: _____ EST

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

Heart

*** TRANSPLANT START:** DATE: _____ TIME: _____ EST
*** REMOVED FROM COLD:** DATE: _____ TIME: _____ EST
*** CLAMPS OFF:** DATE: _____ TIME: _____ EST

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June 8, 2017