

## Clinical Process Instruction Manual

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### Perfusion & Packaging: Lung Process Instruction

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#### 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.

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*
  - *Lung Retrieval Operative Note* (see Exhibit 1) or *DCD Lung Retrieval Operative Note* (see Exhibit 2).
  - *Lung Transplant Operating Room Data* (with attached ABO and Serology). See Exhibit 3.
  - *The HLA Lab Requisition*
  - *Laboratory Services Requisition: STAT/NON-STAT Infectious Disease Testing of Organ Donors* (if required)
  - *Public Health Ontario: General Test Requisition* (if required)
  - Organ Labels
  - Specimen Labels
  - *Lung Donor Data Form* from University Health Network (UHN)
  - Surgical supply list (if needed)
  - Miscellaneous requisition for the Bronchioalveolar Lavage (BAL)

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

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:

## Clinical Process Instruction Manual

---

### Perfusion & Packaging: Lung Process Instruction

---

- 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), 90ml
  - 10 specimen bags
  - 1 hammer (to break up slush if needed)
  - 3 sputum traps
  - 3 – 30ml syringe slip tip
  - 2 Thoracoabdominal (TA) Stapler (size 30)
  - 6 TA reload
  - 2 each venous return cannulas (sizes 12,16,20 & 24)
    - 4 – 21GX1.5” needles
    - 4 – 18Gx1.5” needles
  - 10 microbiology requisitions
  - 1 sterile chest retractor (if not provided at recovery facility)
  - 1 sterile sternal saw (if not provided at the recovery facility)
3. 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 a designated area in the surgical retrieval room.
4. 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 of Perfadex Plus
  - 3 – 1L of Perfadex Plus
  - 3 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 an extra small red styrofoam cooler to contain all unused supplies post-recovery that may require refrigeration. The SRC replaces depleted slush to maintain appropriate inventory of frozen slush, filling from the bottom up.

## Clinical Process Instruction Manual

---

### Perfusion & Packaging: Lung Process Instruction

---

5. The SRC departs for the donor hospital and picks up recovery team at predetermined time and location.

#### Upon Arrival at Recovery Hospital

6. The SRC notifies the PRC of his/her arrival time.
7. The SRC introduces the recovery team to the Operating Room (OR) staff.
8. The SRC records the names of the OR staff (if time permits) and the civic addresses of the donor hospital with contact information on the *Organ Donor Surgery Information*.
9. 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.
10. The SRC reviews the patient's chart with the recovery team to confirm:
  - ABO
  - serology results
  - declarations and consent
  - coroner involvement (if required)

If required, the SRC discusses serology results with the Organ and Tissue Donation Coordinator (OTDC) or Clinical Services Coordinator (CSC).

11. The SRC 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.
12. For the BAL sample that is obtained during the bronchoscopy, the SRC must provide the BAL trap, label the container, and fill out the microbiology requisition with:
  - the TGLN identification number
  - donor date of birth
  - date and time of specimen collection
14. The SRC asks the OR staff for an intravenous (IV) pole for use during perfusion, a table and basin for packaging, and a 18 french foley catheter for retrograde flush. An alternate size may be used as specified by the surgeon.

## Clinical Process Instruction Manual

---

### Perfusion & Packaging: Lung Process Instruction

---

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)

The SRC also opens the perfusion tubing to the scrub nurse, and the distal end of the tubing is secured with a clamp onto the head of the OR table. The remainder of the tubing is passed to the SRC who attaches it to the IV pole provided.

16. The SRC scrubs in, as per the 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
- 2 to 3 bags of crushed slush
- 1 – 1cc vial of Prostin
- 1 – 10cc syringe of NaCl
- 1 – 21GX1.5” needle
- 1 small sterile specimen container

16.1. The SRC places one bag over the sterile basin.

16.2. The SRC places 1 to 2 bags of crushed slush into the bag.

16.3. The SRC places the other two bags over the existing bag of ice.

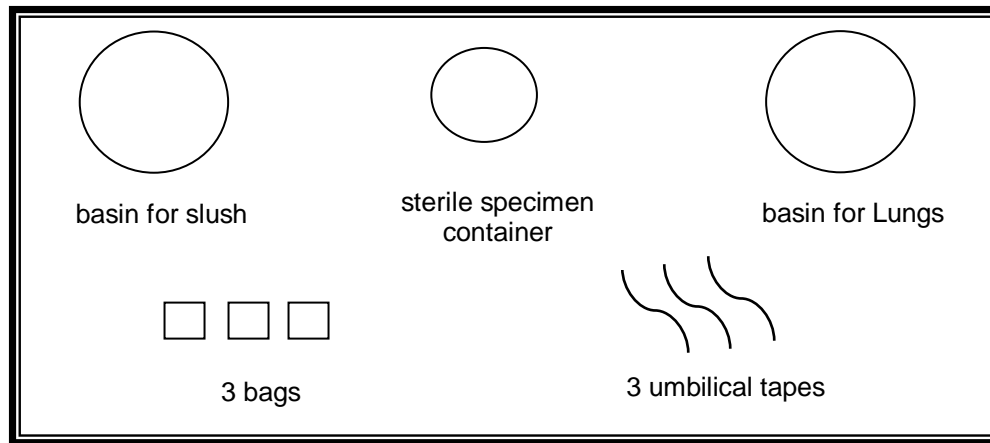
16.4. The circulating nurse is advised to open and pass the sterile syringe of NaCl and 18Gx1.5” needle to the SRC.

16.5. The SRC remains sterile and draws the 1cc of Prostin into 9cc of NaCl, obtaining a 10% Prostin solution. The syringe is placed onto the OR sterile supply table to be used prior to cross-clamp. In the sterile field the needle is switched to a 21G x 1.5” one to prevent glass shards from being re-injected into the bags. The syringe is placed onto the OR sterile supply table to be used prior to cross-clamp.

16.6. The SRC then places 1L to 2L of sterile slush into the second basin to be used to cool the lungs post cross-clamp.

## Clinical Process Instruction Manual

### Perfusion & Packaging: Lung Process Instruction



**Figure 1:** Sterile Back Table Set-up for Lungs

#### Surgical Recovery

17. At commencement of surgical recovery, the SRC records the “skin cut time” on the *Organ Donor Surgery Information*, and notifies the CSC.
18. The SRC will contact the CSC when surgeons have assessed the donor lungs. Accordingly, the CSC contacts the transplant physician upon notification.
19. Upon confirmation of lung quality, the SRC will prepare the Perfadex Plus bags required for perfusion. Each of the 8 litres of Perfadex Plus is injected with the following:
  - In the 3L bags, and 7.5cc of 10% Prostin
  - In the 1L bags, inject 2.5cc of 10% Prostin
20. Four litres should then be labelled “Flush” and further injected with 2.5cc of 10% Prostin solution per litre
21. 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.
22. The SRC records the time of heparin administration and the number of units administered on the *Organ Donor Surgery Information*.

## Clinical Process Instruction Manual

---

### Perfusion & Packaging: Lung Process Instruction

---

23. At cross-clamp, the SRC records the time and begins to perfuse one bag of Perfadex Plus solution. The SRC will continue to flush the remaining 3 litres unless otherwise directed by the thoracic team.
24. The SRC notifies the CSC and provides the cross-clamp time as well as the estimated time of departure from the hospital.
25. The SRC informs the surgical staff when the 3 litres have been emptied. Once 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.
26. Using a pour spout, the SRC decants 3 litres of Perfadex Plus into the sterile basin on the packaging table for the lungs to be stored in.
27. The SRC records name and volume of perfusion solutions and the name of storage solutions on the *Organ Donor Surgery Information*.
28. The SRC obtains a splenic/lymph node sample from surgical staff and it is placed 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*.
29. The surgeon places the lungs into one 3M steri-drape bag on the back table and the top is folded over and secured with umbilical tape. This is repeated with the second and third 3M steri-drape bag.
30. The SRC labels the packaged Lungs as per *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417* and places the organ bag into a large cooler and covers with ice.
31. 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

32. A copy of the *Lung Retrieval Operative Note* (See Exhibit 1) is completed and signed by the appropriate surgical staff and left in the donor chart.

## Clinical Process Instruction Manual

### Perfusion & Packaging: Lung Process Instruction

- 33. Surgical staff may dictate any abnormalities or other comments on the backside of the *Organ Donor Surgery Information*, if necessary.
- 34. The SRC asks the recovery staff to review all documentation and organ label(s). See *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417*.
- 35. The SRC notifies the CSC when they are leaving the recovery hospital.
- 36. The SRC ensures all lot numbers and expiry dates of all solutions and supplies are recorded on the surgical supply list.

#### Post Recovery

- 37. Upon arrival at the transplanting hospital, the SRC delivers the organ to the appropriate OR staff, both signing with date/time of delivery.
- 38. The SRC ensures that the donor blood, BAL, 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*, if required.
- 39. The SRC ensures that the TGLN retractor set and saw are dropped off at Toronto General Hospital (TGH) to be sterilized as per *Sterilization of Equipment – Organ Process Instruction, CPI-9-708*, if used.
- 40. The SRC 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)
Organ Donor Surgery Information	CSF-9-57	PRC	PRC	16 years
Surgical Supply List	CSF-9-58	PRC	PRC	16 years

## Clinical Process Instruction Manual

---

### Perfusion & Packaging: Lung Process Instruction

---

HLA Lab Requisition Form	CSF-9-23	PRC	PRC	16 years
Lung Transplant Operating Room Data	CSF-9-43	PRC	PRC	16 years
Lung Retrieval Operative Note	CSF-9-44	PRC	PRC	16 years
DCD Retrieval Operative Note - Lung	CSF-9-42	PRC	PRC	16 years

#### 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 and Re-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



## Clinical Process Instruction Manual

### Perfusion & Packaging: Lung Process Instruction

#### Exhibit 1: Lung Retrieval Operative Note

#### Page 1

CSF-9-44

UNIVERSITY OF TORONTO LUNG TRANSPLANT PROGRAM

**LUNG RETRIEVAL OPERATIVE NOTE**

Hospital: \_\_\_\_\_ Date: \_\_\_\_\_  
Patient Name: \_\_\_\_\_ Medical Record Number: \_\_\_\_\_  
Surgeons: \_\_\_\_\_

As per routine, the organ donor's chest and abdomen had been previously entered through a midline incision to expose the intra-abdominal and intrathoracic organs. A sternal retractor was inserted and opened to expose the anterior pericardium and medial surface of the pleural spaces bilaterally. A vertical pericardiectomy was made to expose the underlying heart. The heart was assessed by the cardiac transplant surgeon for suitability for transplantation.

Dissection of the inferior vena cava (IVC) 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 and encircled with a heavy silk ligature. Extrapericardial dissection to the level of the azygos vein was performed and a separate silk ligature was placed around the IVC.

The pleural spaces were entered bilaterally to facilitate gross inspection and palpation of the lungs.

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 these great vessels.

In simultaneous heart and lung extractions, a cardioplegic catheter is inserted in the ascending aorta. A 5-0 purse string suture is placed in the main pulmonary artery just proximal to the bifurcation to the left and right main pulmonary vessels. Systemic heparinization is provided by IV injection of a suitable dose of heparin. The hepatic transplant surgeons then insert the hepatic and renal perfusion catheters through the abdominal aorta after transecting the aorta distal to the superior mesenteric artery. The pulmonary arterial catheter is then inserted in the main pulmonary artery and secured with the purse string.

With all transplant surgeons appropriately ready to perfuse their respective organs, a direct injection of 500 micrograms of prostaglandin PGE1 into the main pulmonary artery was made.

When systemic pressure reaches 80 mmHg, the SVC was ligated and IVC transected. The left atrial appendage was transected in order to vent the lungs.

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## Clinical Process Instruction Manual

### Perfusion & Packaging: Lung Process Instruction

#### Exhibit 2: DCD Lung Retrieval Operative Note

Page 1

CSF-9-42

UNIVERSITY OF TORONTO LUNG TRANSPLANT PROGRAM

#### DCD LUNG RETRIEVAL OPERATIVE NOTE

Hospital: \_\_\_\_\_ Date: \_\_\_\_\_  
Patient Name: \_\_\_\_\_ Medical Record Number: \_\_\_\_\_  
Surgeons: \_\_\_\_\_

As per routine, the donor is given 300u/kg of heparin in the ICU. After the withdraw of life sustaining therapy, the ICU team witnesses the cessation of ventilation and circulation for a pre-determined time period. After this pre-determined time, the donor is transferred to the OR where an airway was re-established and a diagnostic bronchoscopy was performed. Only after bronchoscopy is accomplished and no signs of aspiration are observed, ventilation is started. The donor is maintained on a ventilator with 50% FIO<sub>2</sub> through until the lungs are removed. The organ donor's chest and abdomen were entered through a midline incision to expose the intra-abdominal and intrathoracic organs. A sternal retractor was inserted and opened to expose the anterior pericardium and medial surface of the pleural spaces bilaterally. A vertical pericardiectomy was made to expose the underlying heart. Attachments between the main pulmonary artery and ascending aorta were divided to expose and properly separate these great vessels. A 5-0 purse string suture is placed in the main pulmonary artery just proximal to the bifurcation to the left and right main pulmonary branches. The pulmonary arterial cannula is then inserted in the main pulmonary artery and secured with the purse string.

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. The left atrial appendage was transected in order to vent the lungs. The inferior vena cava at the level of the diaphragmatic surface is transected to vent the liver.

Pulmonary flush was then instituted. Through the entire pulmonary flush process, mechanical ventilation was maintained. Cold solution and crushed ice were placed in the pericardial and pleural spaces bilaterally to facilitate hypothermia of the lung bloc. Once the flush solutions had passed through the lung completely, we proceeded to remove the lung bloc.

This was done by elevating the heart out of the pericardial sac and transecting the left atrium just proximal to the confluence with the right and left pulmonary veins. Once the left atrium was completely detached posteriorly, the heart was dropped back into the pericardial sac and the main pulmonary artery was transected just proximal to the bifurcation. The aortic route was dissected and transected at the level of the takeoff of the great vessels with posterior attachments of the aortic route and posterior pericardium transected working backwards into the pericardial sac. The superior vena cava was then transected within the pericardium and the heart removed from the donor pericardial sac.

The pericardium was transected at the diaphragm to enter retropericardial space. Blunt dissection was carried forward along the line of the esophagus and aorta posteriorly up to the level of the trachea just above the carina. The inferior pulmonary ligaments were then transected bilaterally to free up the entire lung bloc inferiorly.

March 12, 2009

