Clinical Process Instruction Manual

Perfusion & Packaging: Kidney Without LifePort™ Pump 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 instructions 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*
    - *Kidney Transplant Operating Room Data* (with attached ABO and Serology)
    - *HLA Lab Requisition Form*
    - *Public Health Requisition* from Public Health (if required)
    - *Laboratory Services Requisition: STAT/ NON-STAT Infectious Disease Testing of Organ Donors* (if required)
    - Organ Labels
    - Specimen Labels
    - *Kidney Retrieval Operative Note*
    - Surgical supply list (when needed)

    For organ recoveries performed by transplant programs, the *Organ Donor Surgery Information* and the *Kidney 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: <u>Separate cooler sheets</u> are required when <u>TGH</u> accepts an organ combination and/or cluster.

2. The SRC or designate prepares the abdominal organ surgical recovery kit. The SRC reviews the contents of the kit to ensure that all of the following required supplies are present:
    - 3 sterile Y perfusion tubing
    - 2 portal tubing (cannula)
    - 15 sterile organ bags

- 4 large organ containers
- 2 red top tubes
- 2 purple top tubes
- 4 yellow top tubes (ACD)
- 5 pour spouts
- 3 specimen containers (non-sterile)
- 10 specimen bags
- 3 sterile specimen containers
- 1 hammer (to break up slush if needed)
- 12 venous return cannulas (sizes 12,14,16, 21 & 24)
- 10 microbiology requisitions
- 1 sterile abdominal retractor (if not provided at the recovery facility)
- 2 blue tamper proof locks

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 supply store room.

4. The SRC obtains 2 red styrofoam coolers from the TGLN surgical supply store room, and lines them with a yellow plastic bag. The SRC then places the following items within the coolers:
   - wet ice (fill 1/3 of the coolers)
   - 7L to 8L of Servator-B.
   - 6 to 10 bags of frozen saline (may break up slush at TGLN or recovery facility)

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

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

6. The SRC picks up the recovery team at a predetermined time and location.

Upon Arrival at Recovery Hospital

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

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

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

10. The SRC reviews the patient's chart with the recovery team and confirms:
    - ABO,
    - serology results,
    - declarations (if applicable),
    - consent and Coroner involvement, if required

    If required, the SRC discusses serology results with 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,
    - date and time of collection.

    The samples are to be placed into specimen bags containing the appropriate requisitions.

12. The SRC asks the OR staff for 1 or 2 intravenous (IV) poles for use during perfusion, a table, and 2 sterile basins for abdominal ice and kidney packaging.

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

14. The SRC opens the following sterile supplies to the scrub nurse to remain on the OR supply table:
    - 1 sterile abdominal retractor (if not provided by the OR)
    - 1 venous return cannula (size to be determined by surgical staff if needed)
    - 2 sterile Y perfusion tubing sets
    - portal tubing (cannula)

15. Prior to use, the frozen saline must be wrapped in a towel and hammered until broken up into a slush-like consistency.

16. The SRC 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
    - 4 CardioMed organ bags
    - 2 large organ containers
    - 6 to 10 bags of crushed slush
    - 1 sterile specimen container
    - 1 1L Ringer's Lactate or normal saline

Clinical Process Instruction Manual

Perfusion & Packaging: Kidney Without LifePort™ Pump Process Instruction

NOTE: If possible, using a sterile marker supplied by the donor OR, it is suggested to label the organ containers as Left or Right, as deemed necessary.

The SRC empties 1 to 2 bags of crushed slush into an empty sterile basin. Cold saline is to be added to the slush post cross-clamp. The remaining bags of slush are to be opened and emptied into the other sterile basin. This slush is to be used for abdominal cooling post aortic cross-clamp and should be located in close proximity to the OR table to ensure accessibility. The SRC removes the tops of the large organ containers and places them close to the table edge.

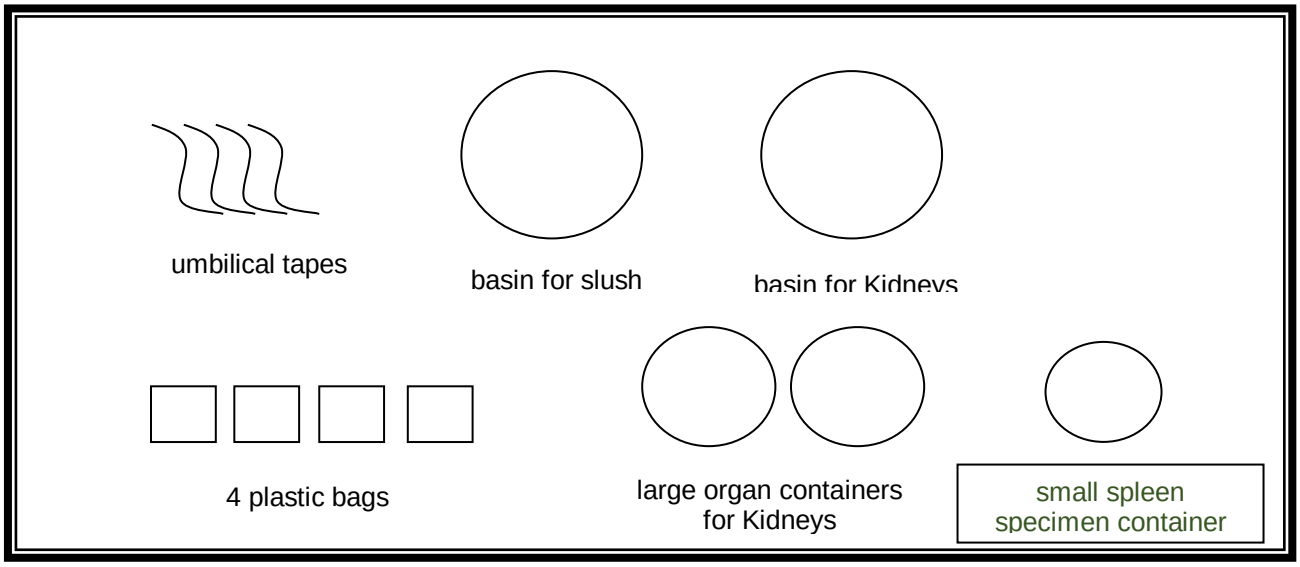


Figure 1: Sterile Back Table Set-up of Kidneys without LifePort™ Pump

17. The SRC breaks scrub and opens the sterile perfusion tubing to the scrub nurse. The SRC will then direct the scrub nurse to attach the portal cannula to the distal end of one of the sterile Y perfusion tubing sets. The SRC directs the scrub nurse to attach the aortic cannula to the distal end of the other sterile Y perfusion tubing set.

18. The SRC attaches the other ends of both the aortic and the portal perfusion lines to 2 separate IV poles. To avoid confusion, these lines may be labelled “aortic” and “portal” using tape and a marker.

19. Both sets of perfusion tubing are separately attached to the foot of the OR table by the scrub nurse.

20. With the aid of the scrub nurse, the SRC uses the perfusion solution to flush both the aortic and portal lines to ensure that all air is removed.

Clinical Process Instruction Manual

Perfusion & Packaging: Kidney Without LifePort™ Pump Process Instruction

Surgical Recovery

21. Upon commencement of surgical recovery, the SRC records the "skin cut time" on the *Organ Donor Surgery Information*, and notifies the CSC.

22. The SRC will contact the CSC when surgeons have assessed the donor kidney(s). Accordingly, the CSC contacts the transplant physician upon notification if required.

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

24. When cross-clamp is imminent, the SRC hangs 1 – 1L and 1 – 2L bag Servator-B depending on surgeon preference on the aortic line and 1 – 2L bag Servator-B on the portal line. The perfusate amounts are subject to change as per request from the surgical staff.

25. At cross-clamp, the SRC records the time and opens both the aortic and portal perfusion lines. The SRC will notify the surgical staff as each litre of perfusate is used and stops perfusion upon request.

26. The SRC notifies the CSC of cross-clamp time and estimated time of departure.

27. Using a pour spout the SRC decants 1L Servator-B equally into each large organ container on the packaging table, (more than 500ml may be required). Each kidney will be packaged with the organ container and lid secured by the surgeon.

28. The SRC will verbally confirm with the surgeon which side Kidney (i.e. Left kidney in Left Jar) is being placed in each jar.

29. The jar is then placed in one CardioMed organ bag by the surgeon with the top tied off and tightly secured with umbilical tape.

30. The above bag containing the jar is then placed in a 2nd CardioMed bag by the surgeon; the top is tied off and tightly secured with umbilical tape.

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

32. If the surgical staff require vessels, the SRC will obtain them in accordance with *Coordination and Recovery of Adjunct Vessels for use in Solid Organ Transplants, CPI-9-1007* and may be placed in the same cooler as the organ.

33. Once each kidney is appropriately packaged, the SRC labels the organ as per *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417.* The SRC will verify which side kidney is being labelled with the surgeon prior to affixing the label.

34. Each kidney is placed into its own separate red styrofoam cooler and sufficiently covered with ice. It is recommended that the SRC place a label on the outside of the red cooler indicating which organ is contained.

35. The SRC ensures that all labels are completed appropriately.

36. If unaccompanied by a member of the recovery team to the recipient OR, the SRC secures the coolers 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

37. Surgical staff may document any abnormalities or other comments on the backside of the *Organ Donor Surgery Information*, if necessary. These comments may also be made on each *Kidney Transplant Operating Room Data.* The SRC and/or recovery surgeon will also inform the transplant surgeon directly from the OR any issues with the perfusion of the kidney.

38. The SRC ensures that the recovery surgeons sign the *Kidney Retrieval Operative Note* and leave this in the donor's hospital chart.

39. The SRC ensures all lot numbers and expiry dates of all solutions and supplies used are recorded on the surgical supply list.

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

Post Recovery

41. Upon arrival at the transplanting hospital, the SRC delivers the organ to the appropriate OR staff and signs in date/time/receiving organ.

42. 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,* if required.

43. The SRC ensures that the TGLN retractor set is dropped off at Toronto General Hospital to be sterilized as per *Sterilization of Equipment* – Organ *Process Instruction, CPI-9-708,* if used.

44. 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)
Surgical Supply List	CSF-9-58	PRC	PRC	16 years
Kidney Transplant Operating Room Data	CSF-9-52	Hospital	Hospital	16 years
Organ Donor Surgery Information	CSF-9-57	PRC	PRC	16 years
HLA Lab Requisition Form	CSF-9-23	PRC	PRC	16 years
Kidney Retrieval Operative Note	CSF-9-53	PRC	PRC	16 years

References:

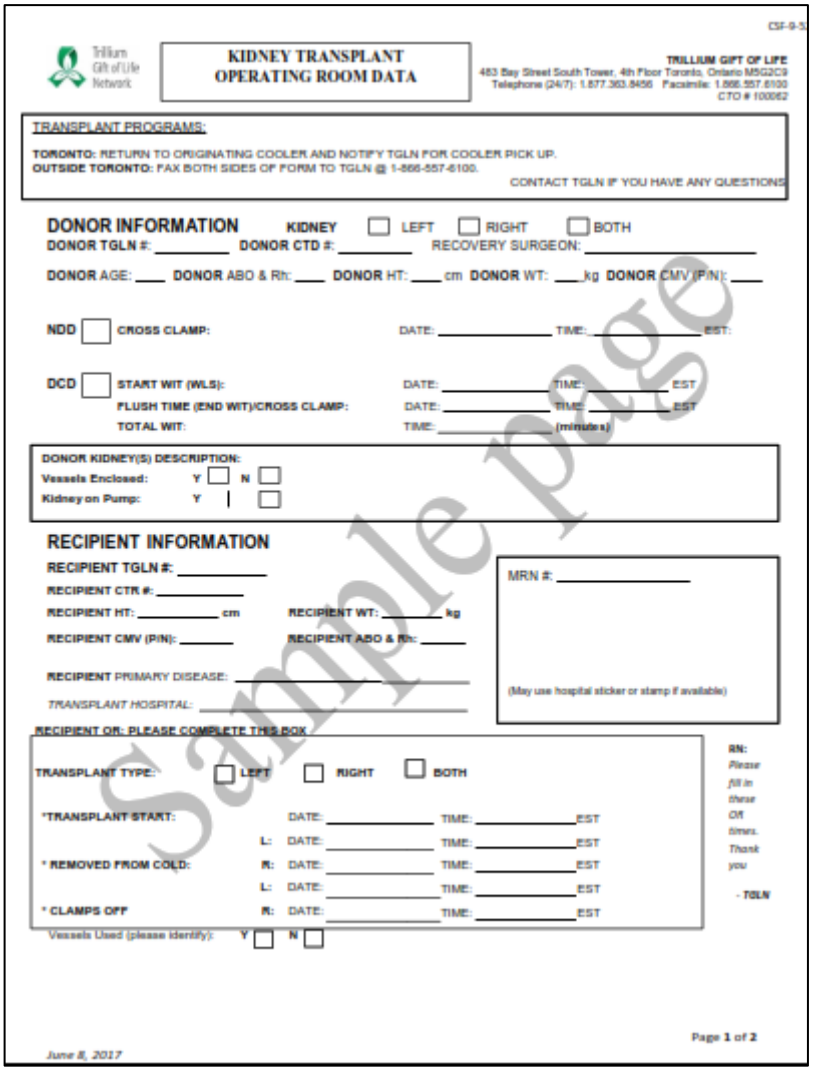
- *Infectious Disease Testing – STAT Process Instruction, CPI-9-211*
- *Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213*
- *Microbiology Testing Process Instruction, CPI-9-214*
- *Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406*
- *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417*
- *Sterilization of Equipment – Organ Process Instruction, CPI-9-708*
- *Coordination and Recovery of Adjunct Vessels for use in Solid Organ Transplants, CPI-9-1007*

- Safety of Human Cells, Tissues and Organs for Transplantation Regulations, Health Canada, June 2007

Clinical Process Instruction Manual

Perfusion & Packaging: Kidney Without LifePort™ Pump Process Instruction

Exhibit 1: Kidney Transplant Operating Room Data



CSF-9-5

Trillium Gift of Life Network

KIDNEY 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 KIDNEY ☐ LEFT ☐ RIGHT ☐ BOTH
DONOR TGLN #: _____ DONOR CTD #: _____ RECOVERY SURGEON: _____
DONOR AGE: ___ DONOR ABO & Rh: ___ DONOR HT: ___ cm DONOR WT: ___ kg DONOR CMV (P/N): ___

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

DCD ☐ START WIT (WLS): DATE: _____ TIME: _____ EST
FLUSH TIME (END WIT)/CROSS CLAMP: DATE: _____ TIME: _____ EST
TOTAL WIT: TIME: _____ (minutes)

DONOR KIDNEY(S) DESCRIPTION:
Vessels Enclosed: Y ☐ N ☐
Kidney on Pump: Y | ☐

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 TYPE: ☐ LEFT ☐ RIGHT ☐ BOTH

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

Vessels Used (please identify): Y ☐ N ☐

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

Sample page

Page 1 of 2

June 8, 2017

Clinical Process Instruction Manual

Perfusion & Packaging: Kidney Without LifePort™ Pump Process Instruction

Exhibit 2: Kidney Retrieval Operative Note

CSF-9-53

UNIVERSITY OF TORONTO KIDNEY TRANSPLANT PROGRAM

KIDNEY RETRIEVAL OPERATIVE NOTE

Hospital: _____ Date: _____

Patient Name: _____ Medical Record Number: _____

Surgeons: _____

The patient was aseptically prepped and draped in the usual sterile fashion. A midline incision was made from the sternal notch down to the pubic bone. The abdominal incision was continued and the peritoneal cavity was entered. A brief exploratory laparotomy was then performed and the abdominal organs are carefully inspected for suitability and for other abnormal pathology or trauma.

The small intestines were retracted, and the peritoneum over the Inferior Vena Cava (IVC) was incised and the cava exposed up to the level of the left renal vein. The superior mesenteric artery was exposed at this level and a free tie placed around it. The inferior mesenteric artery (IMA) was identified and divided between ties. The aorta was freed up at the level of the IMA and a free tie was placed around it. Dissection then continued across the porta hepatis. The supraduodenal vessels were ligated with ties. The gastroduodenal artery was identified and ligated. Dissection continued along the superior border of the pancreas and the splenic artery was identified. The splenic artery was divided between ties. The left gastric artery and vein were identified and if there was no evidence of an aberrant left artery, they were divided between ties. The crura of the diaphragm were then divided and the aorta was exposed at the hiatus. Dissection of the aorta continued until the take-offs of the celiac axis and the superior mesenteric artery were exposed.

The portal vein was exposed and the confluence of the superior mesenteric vein and splenic vein was identified. A free tie was placed around the superior mesenteric vein. Lastly, the IVC was exposed and the left and right renal veins were identified.

The patient was then fully heparinized. The distal aorta was ligated and a cannula was placed in the aorta at the level of the IMA. In conjunction with other retrieval teams, the flush proceeded. Crushed ice was placed on kidneys and throughout the abdominal cavity. The IVC was divided above the renal veins. Perfusion to the kidneys was then re-established by placing a vascular clamp on the aorta. After identifying and immobilizing each of the ureters, renal veins and arteries, the kidneys were removed. Each graft contained a portion of aortic cuff and IVC. The kidneys may have been recovered separately in situ, or recovered en bloc and dissected further outside of the body. On the sterile back table a small section of renal capsule was dissected from each kidney to ensure efficient perfusion and exclude any abnormal pathology. A portion of spleen was removed for HLA typing.

ADDITIONAL NOTES

Aberrant Vessels: _____

Organs Retrieved: _____

Other: _____

Signature: _____

March 29, 2023

Clinical Process Instruction Manual

Perfusion & Packaging: Kidney Without LifePort™ Pump Process Instruction

Exhibit 3: DCD Kidney Retrieval Operative Note

CSF-9-51

UNIVERSITY OF TORONTO KIDNEY TRANSPLANT PROGRAM

DCD KIDNEY RETRIEVAL OPERATIVE NOTE

Hospital: _____ Date: _____

Patient Name: _____ Medical Record Number: _____

Surgeons: _____

As per routine, the donor is given _____ u 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, prepped and draped in the usual sterile fashion. A midline incision was made from the sternal notch down to the pubic bone. The abdominal cavity was entered, the intestines were retracted medially, and the peritoneum over the Inferior Vena Cava (IVC) and abdominal was incised. The distal aorta was encircled and ligated, and a cannula was inserted immediately and the IVC opened anteriorly.

The crura of the diaphragm were divided and the supraceliac aorta was clamped and the cold perfusion started. Crushed ice was placed on the liver and both kidneys.

After adequate cold perfusion the ureters were identified and dissected with the surrounding tissues and divided distally. The distal aorta was dissected up to the left renal vein. The left renal vein was divided with a cuff of the IVC and mobilized to the left. The aorta was then opened anteriorly and identification of the origin of both renal arteries was accomplished. The aorta was then divided posteriorly and split into both sides.

After identifying the ureters and renal vessels on both sides, both kidneys were dissected out from the surrounding tissues and removed with the aortic patch.

On the sterile back table, each kidney was dissected further to ensure adequate perfusion and to exclude abnormal pathology.

A specimen of spleen was taken for HLA typing.

Mass closure of the skin began after removing all the ice and all the instruments and insuring correct sponge and instrument count.

ADDITIONAL NOTES

Aberrant Vessels: _____

Organs Retrieved: _____

Other: _____

Signature: _____

March 29, 2023