Clinical Process Instruction Manual

Perfusion & Packaging: Kidney with 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 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.

Ontario deceased donor kidneys are placed on kidney pumps as the primary organ preservation method with the exception of the following:

- Standard Criteria Donor / Death Determination by Neurologic Criteria (SCD/DNC) kidneys allocated within the local region
- Pediatric donor kidneys
- Kidney/Pancreas donor kidneys

Note: The Ottawa Hospital has requested to use pumps for all kidneys.

Under exceptional circumstances, transplant programs may request an exemption to use kidney pumps for locally allocated SCD/DNC kidneys. In these cases, transplant programs must request a kidney pump from TGLN at the time of offer and provide a medical rationale for the request (e.g. long expected cold ischemic time, organ quality).

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). See Exhibit 1.
    - *HLA Lab Requisition Form*
    - *Public Health Requisition* from Public Health (if required)
    - *Laboratory Services Requisition: STAT Infectious Disease Testing of Organ Donors* (if required)
    - Exterior and Interior Organ Labels

- Specimen Labels
- *Kidney Retrieval Operative Note* (See Exhibit 2) or *DCD Kidney Retrieval Operative Note* (See Exhibit 3)
- 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: Separate cooler sheets are required when TGH accepts an organ combination and/or cluster.

2. The SRC or designate prepares the abdominal organ surgical recovery kit and a kidney pump kit. The SRC reviews the contents of the kits to ensure that all of the following required supplies are present:

   The following are contained in the abdominal recovery bag:
   - 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, 16, 21 & 24)
   - 10 microbiology requisitions
   - 1 sterile abdominal retractor (if not provided at the recovery facility)
   - 2 blue tamper proof stickers

   The Pump Kit:
   - 2 Kidney perfusion circuits
   - 4 – 7X20 seal rings
   - 4 – 10X30 seal rings
   - 4 – Universal Seal Ring Cannula 3 mm
   - 4 – Universal Seal Ring Cannula 5 mm
   - 4 – Universal Seal Ring Cannula 7 mm
   - 4 – Universal Seal Ring Cannula 9 mm
   - 5 sterile drapes

- 1 – power cord
- 2 LifePort™ Pumps

3. The SRC verifies the following LifePort™ pre-check steps are completed:
   - Pump turns on and all display panels are functioning on battery power only
   - The spring latch is intact and not loose or bent
   - Lid seals and latches correctly
   - No severe damage to the handles or exterior

   If any of these steps cannot be completed or indicate that pump may not be functioning correctly, the SRC will not use the pump. The SRC will document in the *Equipment Repair/Annual Equipment Service Log* that the kidney pump is unusable. In addition, the SRC will notify the Manager, Surgical Recovery Services (Organ) and Administrative Assistant (PRC Organ) to ensure the pump is sent for repair. While awaiting shipment, the SRC places a notice on the kidney pump to ensure it is not used.

4. The SRC will remove the ice bucket from each LifePort™ and fill it with ¼ ice, ¼ water, ¼ ice and then ¼ water. One litre bag of KPS-1 or MPS can be placed in each of the ice buckets. The SRC replaces the ice buckets, places the lid on the LifePort™ and secures it ready for transport.

5. 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.

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

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

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

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

Upon Arrival at Recovery Hospital

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

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

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

12. The SRC reviews the patient's chart with the recovery team, confirms ABO, serology results, declarations, 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).

13. The SRC ensures all appropriate blood samples have been drawn and correctly labelled with a 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 asks the OR staff for 2 intravenous (IV) poles for use during perfusion, a table, and 2 sterile basins for abdominal ice and kidney packaging.

15. 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). A second cannula is required if the liver is being recovered at the same time.
    - 1 sterile Y perfusion tubing sets. A second perfusion tubing set is required if the liver is being recovered at the same time.
    - Portal Tubing (cannula)
    - 2 LifePort™ perfusion circuits. The circuits should only be opened after it has been determined that the kidney(s) are suitable for transplant.
    - LifePort™ cannulas – size to be determined by surgeon, after cross-clamp

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

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
    - 1 – 2 L normal saline
    - 2 circuits
    - 6 to 10 bags of crushed slush
    - 1 small sterile container

The SRC empties at least three 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 lids from the circuits are removed and kept on the sterile field. The cradles are removed and kept on the sterile field.

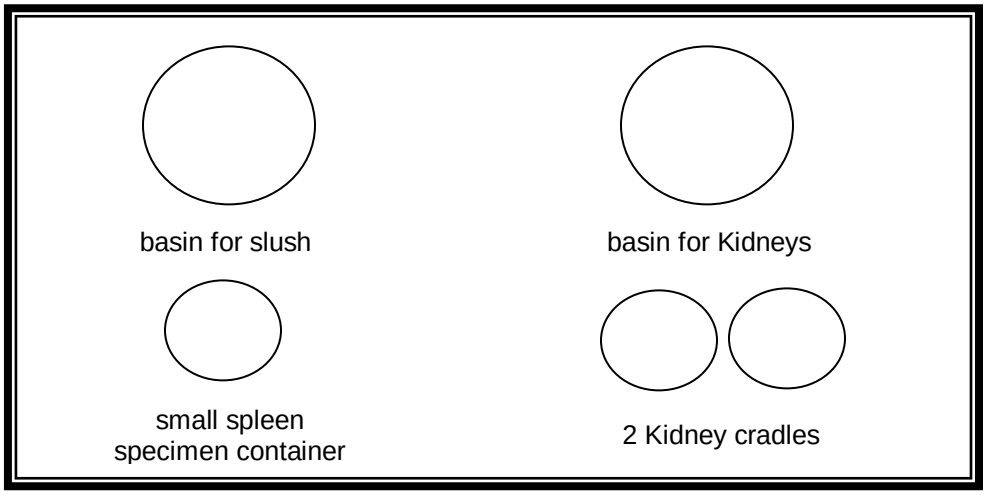

Figure 1: Sterile Back Table Set-up of Kidney with LifePort™ Pump

18. The SRC or designate breaks scrub (if scrubbed in) and decants 1 L of KPS-1 or Servator-M into the circuit. The lids are replaced onto the circuits and the circuits are handed off the sterile field and placed in the pump to circulate. The SRC presses wash (recommended 20 minutes prior to organ recovery). At this point, an effort should be made to clear any bubbles from the tubing of the circuit. The TGLN number and ABO are entered into the pump.

19. A recipient transplant program may request an additive (e.g. Verapamil) be added to the kidney pump to improve perfusion. The additive request and dose will be documented by the CSC on *Reporting Form: Clinical Services Coordinator to Surgical Recovery Coordinator*. If requested, the SRC will ask the anaesthesiologist for the required dose of the additive. The additive can be added at any time during the setup of the pump or after the kidney has been placed in the pump. The additive should be drawn into a syringe and injected into the cassette after it is filled with solution.

20. The SRC opens the sterile perfusion tubing to the scrub nurse. The SRC then directs the scrub nurse to attach the aortic cannula to the distal end of one of the sterile Y perfusion tubing set. A

portal cannula is necessary if the liver is being recovered and will need to be connected to the other sterile Y perfusion tubing set.

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

Surgical Recovery

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

23. 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.

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 2 – 1L and 2 – 2L bag of Servator-B depending on surgeon preference on the aortic line and 2 – 1L bag of Servator-B on the portal line. The perfusate amounts are subject to change as per request from the surgical staff. The perfusion solution bags being infused into the aorta are put into pressure bags and pumped up to about 100 mmHg. The SRC will continue to monitor the pressure and pump the pressure bags up to ensure a continuous pressure of 100 mmHg.

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

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

28. The surgeon removes the kidney(s) and places in slush.

29. The surgeon cannulates the kidney(s) on the back table in a basin. The surgeon puts the kidney in the LifePort™ perfusion cradle.

30. The SRC removes the transporter lid and removes the outer circuit lid. The SRC places the circuit lid upside down to the side. The SRC or designate provides the sterile drape to the surgeon in the sterile field. The surgeon uses aseptic technique to drape the transporter, push the STOP button then remove the inner organ circuit lid. The surgeon places the kidney into the circuit.

31. The surgeon inspects the cannula. After inspection, the surgeon connects the kidney to the circuit. Once the kidney is connected, the surgeon removes the end cap.

32. The surgeon presses the PRIME button on top of the sterile drape. The surgeon tilts the cannula for bubble removal.

33. The surgeon replaces the end cap. The pump will beep, and then stop. In the event that the pump does not stop, a leak is present. The surgeon attempts to fix the leak before proceeding.

34. The surgeon presses the INFUSE button. The pump speeds up as the kidney expands.

35. The surgeon covers the kidney with a net and checks the parameters on the outer display for: pressure, flow, vascular resistance and temperature.

36. The SRC verifies that the transporter is in Infuse mode. The surgeon or scrub nurse replaces the inner sterile cover, removes the drape and the SRC places the outer circuit lid. The appropriate interior organ label is placed on the exterior of the circuit. The SRC will ensure that the correct kidney has been recorded on the documents that will travel with the transporter (e.g. allocated kidney to specific transplant program). The SRC then closes the transporter lid. All accompanying documents will be secured to transporter lid in the pouch provided.

37. If 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.

38. 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*.

39. The SRC ensures that all labels are completed appropriately. The SRC records names of perfusion and storage solution on *Organ Donor Surgery Information.*

Prior to Departing Recovery Hospital

40. Surgical staff may document any abnormalities or other comments on the *Organ Donor Surgery Information*, if necessary. These comments may also be made on each *Kidney Transplant Operating Room Data*.

41. The SRC and the OR staff review all documentation and organ labels.

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

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

44. Th SRC notifies the PRC and provides the information from step 39, as well as their time of departure.

45. If the pump is not running correctly or if there are any perfusion issues with the kidney, the SRC informs the CSC for documentation in the clinical notes. The SRC and/or recovery surgeon also informs the accepting transplant program directly from the donor OR to indicate whether the issue is pump or organ-related.

46. The SRC checks the ice level in the LifePort™ and adds additional ice, as required before the pump is transported to the transplant program.

47. The SRC places and secures the lid on the LifePort™.

48. The SRC initials in the box provided on the tamperproof label and attaches it to the LifePort™ in a fashion that covers the gap between the lid and machine. See Exhibit 4, sample kidney pump tamperproof label. The SRC may document the tamperproof label number on the *Organ Donor Surgery Information*.

49. The SRC secures the LifePort™ on the cart with the clip provided, if used.

Post Recovery

50. When the SRC drops off the LifePort™ pump, he/she ensures there is a sterile drape that accompanies the pump for use in the recipient OR (if requested).

    50.1 After the transplant, the SRC picks up the LifePort™ at the recipient hospital. Prior to departing the hospital, the SRC ensures that the circuit has been removed and that the ice bucket has been emptied. She/he brings it back to TGLN. The SRC will ensure that it is cleaned properly with the approved disinfectant solution and the *Disinfection Label,* “I am clean”, is attached to the pump dated and initialed.

51. The SRC verifies the following LifePort™ post-check steps are completed:
    - ensures no significant damage to the LifePort™ (e.g., display panel not displaying, lid not sealing, battery cover not flush with unit)
    - ensures that the power cord can be inserted
    - ensures data cable can be inserted

52. If any of these steps cannot be completed or indicate that the pump may not be functioning correctly, the SRC will mark the pump as “Out of Service”. The SRC will document in the *Equipment Repair/Annual Equipment Service Log* that the kidney pump is unusable. In addition, the SRC will

notify the Manager, Surgical Recovery Services (Organ) and Administrative Assistant (PRC Organ) to ensure the pump is sent for repair.

53. The SRC uses the computer in the SRC room to download the data/activity report on each LifePort™ and places this report in the corresponding donor chart. Please ensure the TGLN case number is documented in the downloaded file.

54. The SRC ensures the LifePort™ pumps are plugged in to re-charge the batteries.

Illustration 1: LifePort™ Kidney Transporter

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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	PRC	PRC	16 years
Organ Donor Surgery Information	CSF-9-57	PRC	PRC	16 years
Kidney Retrieval Operative Note	CSF-9-53	PRC	PRC	16 years
Kidney DCD Retrieval Operative Note	CSF-9-51	PRC	PRC	16 years
HLA Lab Requisition Form	CSF-9-23	PRC	PRC	16 years
Laboratory Services Requisition: STAT/NON-STAT Infectious Disease Testing of Organ Donors	CSF-9-20	PRC	PRC	16 years

References:

- *Pulsatile Perfusion Pumps Process Instruction, CPI-9-401*
- *Transportation Coordination Process Instruction, CPI-9-404*
- *Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406*
- *Equipment Maintenance Process Instruction, CPI-9-426*
- *Coordination and Recovery of Adjunct Vessels for use in Solid Organ Transplants, CPI-9-1007*

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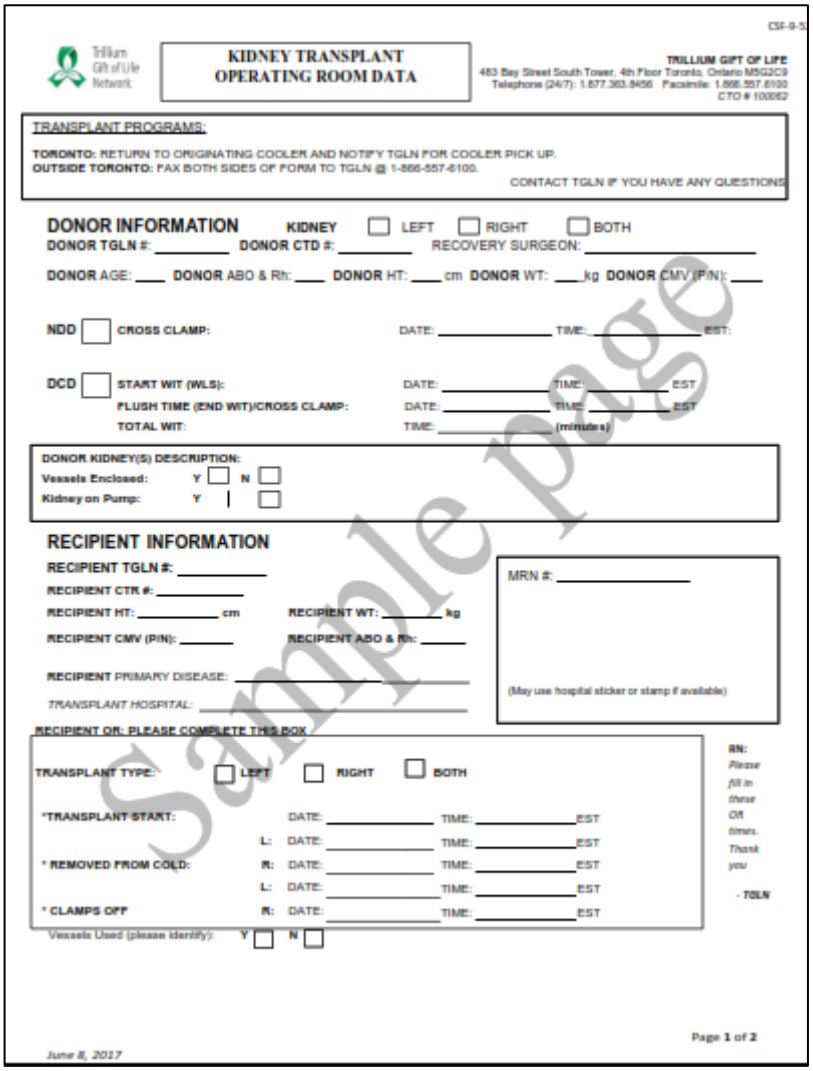
Exhibit 1: Kidney Transplant Operating Room Data



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 ☐ N ☐

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

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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

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

Exhibit 4: Sample Kidney Pump Tamperproof Label