Ontario Health
Trillium Gift of Life Network

Clinical Process Instruction Manual

Perfusion & Packaging: Kidney Perfusion with LifePort™ Pump – Eastern 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*.

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:

Arriving at the Ottawa Hospital (TOH)

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

2. The SRC obtains the appropriate documentation required for recovery. The following forms and labels are located in TGLN's office at the Civic Campus. Forms include:
    - *Organ Donor Surgery Information*
    - *DNC Case: Kidney Retrieval Operative Note*
    - *DCC Case: DCD Kidney Retrieval Operative Note*
    - *Interior Label*
    - *Exterior Label*
    - *Specimen Labels*
    - *Surgical Supply List*

    An iTransplant laptop is available in TGLN's office at the Civic Campus.

3. Additionally, the SRC obtains the following documents/forms from PRC:
    - *Kidney Recipient Transplant Operating Room Data form (with ABO and Serology) x 2.*
    - *Confirmation of delivery*
    - *Reporting Form: Clinical Services Coordinator to Surgical Recovery Coordinator (if available)*
    - *HLA Lab Requisition Form (when applicable)*
    - *Laboratory Services Requisition: STAT Infectious Disease Testing of Organ Donors (if required)*

4. The SRC informs the PRC if all documents were received.

5. The SRC ensures that the LifePort™ machines and all the supplies have been delivered to the appropriate operating room:
   - General Campus: LifePort™ and supplies/Organ Donor Cart
   - Civic Campus: LifePort™ cart and supplies/Organ Donor Cart

6. The SRC ensures that ice is available. If not:
   - General Campus: obtain ice from ice machine in sterile core Pharmacy area.
   - Civic Campus: call housekeeping 1-4242 for a large container of ice.

7. The SRC verifies the Organ Donor Cart (General Campus) or the LifePort™ Cart and Donor Cart (Civic Campus) to ensure that all of the following required supplies are present:
   - 1 sterile Y perfusion tubing (“Liver Administration Set”)
   - 1 arterial cannula – size to be determined by the surgeon
   - 1 venous cannula, as necessary – size to be determined by the surgeon
   - 2 to 4 pour spouts
   - 2 seal rings - size to be determined by the surgeon
   - 2 straight cannula - size to be determined by the surgeon
   - 2 sterile drapes
   - 2 Kidney perfusion circuits
   - 2 LifePort™ Pumps
   - 1 hammer (to break up slush, if necessary)

8. The SRC asks the OR staff for:
   - 1 intravenous (IV) poles for use during perfusion
   - 1 surgical back table
   - 1 large table to accommodate the LifePort™
   - 2 sterile basins for abdominal ice and kidney packaging
   - Slush machine and 50% alcohol (from fridge) or Hush Slush machine from elevator room at the Civic Campus
   - Slush basin drape

9. The SRC obtains the following items from the Pharmacy:
   - 6L to 8L of HTK (histidine-tryptophane-ketogluterate)
   - 1L to 2L of saline solution for ice machine
   - 2 L of KPS-1

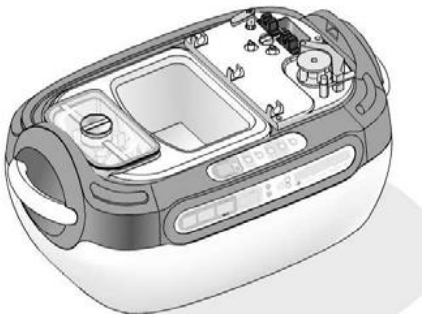
- Bags of frozen saline (if more slush is needed, and as required)

10. The SRC confirms that all sealed items have not been tampered, 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.

11. 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 the 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 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.

12. The SRC will remove the ice bucket from each LifePort™ and fill it with ⅓ ice, ⅓ water, then ⅓ ice. The SRC replaces the ice buckets, places the lid on the LifePort™ and secures it ready for transport. The ice containers on the LifePort™ transporters need to be filled immediately with crushed or cubed ice to start the chilling process.



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

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

15. The SRC 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 discusses serology results with Organ and Tissue Donation Coordinator (OTDC) or Clinical Services Coordinator (CSC).

16. If the donor is a donation after cardio-circulatory death (DCC) donor, confirm the withdrawal of life support time from the donor coordinator. Ensure the operating room is completely set up and the surgical team is scrubbed and ready to receive the patient. The patient's chart must be checked well before the DCC patient arrives as there will be no time when the patient arrives. Check the patient's chart for surgical consent for removal of kidneys and any other relevant data.

17. 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, if applicable. If DCC, the SRC ensures this is done before withdrawal of life support.

18. The SRC opens the following sterile supplies to the scrub nurse (using aseptic technique) to remain on the OR supply table:
    - 1 sterile Y perfusion tubing (*Liver Administration Set*)
    - 1 arterial cannula – size to be determined by the Surgeon

19. The SRC will direct the scrub nurse to attach the aortic cannula to the distal end of the sterile Y perfusion tubing. The perfusion tubing is then attached to the foot of the OR table by the scrub nurse.

20. The SRC will not open the LifePort™ perfusion circuits, cannula, and drapes until the surgeon is satisfied that the case will proceed.

21. Ensure that sufficient slush (1 to 2 litres of saline) is prepared for the procedure. If required, additional bags of frozen saline should be obtained and hammered into a slush-like consistency.

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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 the 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 Servator-B or HTK on the aortic line. The perfusate amounts are subject to change as per request from surgical staff.

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

27. For Death Determination by Neurologic Criteria (DNC), the SRC records the cross-clamp time on the *Organ Donor Surgery Information*. For DCC, the SRC records the cross-clamp time and the flush time on the *Organ Donor Surgery Information.*

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

29. If the surgeon is satisfied that the case will proceed, the SRC opens the following LifePort™ sterile supplies for the scrub nurse using aseptic technique:
    - 2 LifePort kidney perfusion circuits (1 for each LifePort™)
    - 2 cannulas – size to be determined by the surgeon
    - 2 LifePort drapes (1 for each LifePort™)

30. The SRC will decant 1 litre of KPS-1 or Servator-M solution into each LifePort™ cassette. The cassettes are on the sterile field at this point. The scrub nurse keeps the kidney cradles on the sterile field. The scrub nurse will replace the inner lid and the outer lid and then pass the perfusion circuit off the sterile field. These are then placed into the LifePort™ by the SRC.

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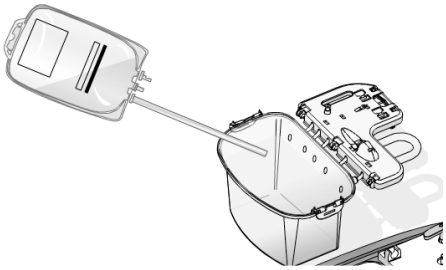
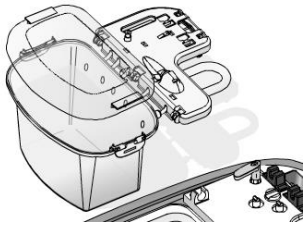
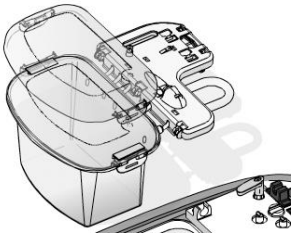
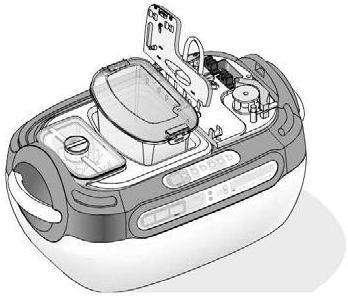
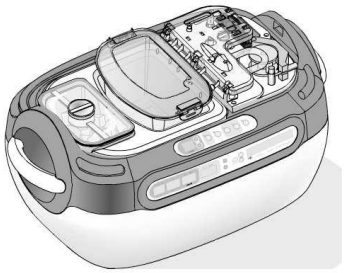
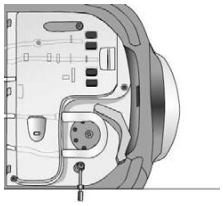
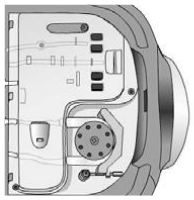
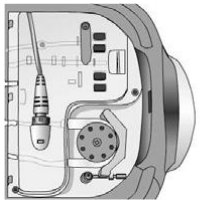
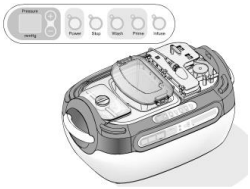




31. The cassettes are placed in the ice container in the LifePort™ by the SRC. The tube frame must be perpendicular to the pump deck and the hinges must be positioned inside of the receivers on the pump deck. Keeping the hinges in place, turn the tube frame down flat onto the pump deck.

32. The SRC opens the pump head and stretches the tubing over the wheel. The SRC closes and latches the pump head raceway to clamp the tubing. She/he rotates the pump deck locking arm 90º and snaps into place. She/he connects the pressure sensor cable from the pump deck to the connector on the tube frame. She/he presses the POWER button on the control panel to energize the unit. The SRC checks the outer display and verifies that the top line reads “Ready”. See the Illustration 4 below.

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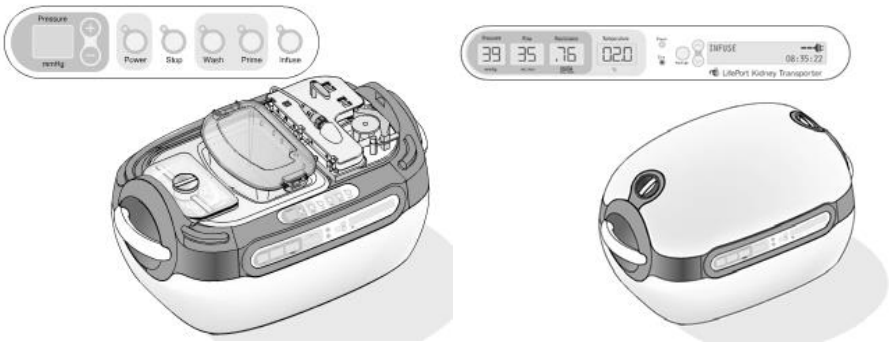
33. The SRC presses the WASH button to circulate perfusate during travel and until ready to receive the kidney. Grasping both handles, lift and gently rotate the Transporter to remove air from the perfusion circuit. Close and latch the cover.



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

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

36. 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.

37. The SRC removes the transporter lid and removes the outer cassette lid. The SRC places the cassette lid upside down to the side.

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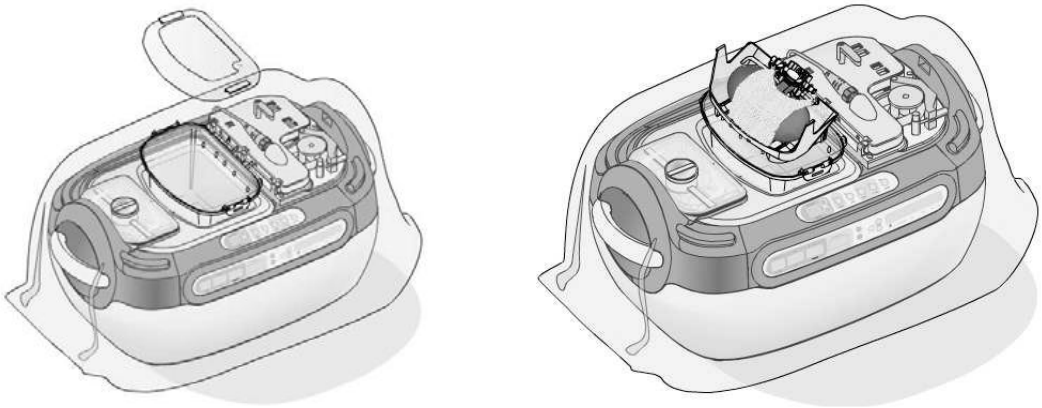
38. The surgeon uses aseptic technique to drape the transporter, push the STOP button, then remove the inner organ cassette lid. The surgeon places the kidney into the circuit.



39. 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.

40. The SRC presses the PRIME button under the sterile drape. The surgeon tilts the cannula for bubble removal.

41. 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.

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

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

44. The SRC verifies that the transporter is in Infuse mode. The surgeon or scrub nurse replaces the inner sterile cover and the SRC places the outer cassette lid. The SRC affixes the inner organ label to the outer cover then closes the transporter lid. Prior to transporting the transporter, the SRC monitors for stability. All accompanying documents will be secured to transporter lid in the pouch provided with the Exterior Organ Label clearly visible.

45. 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*.

46. 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*.

47. The SRC ensures that all labels are completed appropriately. The SRC records names & amounts of perfusion solutions and the name of storage solution on the *Organ Donor Surgery Information.*

Prior to Departing TOH

48. 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 Recipient Transplant Operating Room Data*.

49. The SRC and the OR staff review all documentation and labels.

50. The SRC ensures that the recovery surgeons sign the *Kidney Retrieval Operative Note* form.

51. The SRC ensures lot numbers and expiry dates of all solutions and supplies used are recorded on the *Surgical Supply List.*

52. The SRC notifies the PRC and provides the information from step #47, as well as their time of departure.

53. 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.

54. The SRC checks the ice level in the LifePort™ and adds additional ice, as required before the pump is transported to the transplant program. See Appendix 1.

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

56. 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 in CPI-9-414 Perfusion and Packaging: Kidney Perfusion with Lifeport Pump, sample kidney pump tamperproof label. The SRC may document the tamperproof label number on Organ Donor Surgery Information.

57. The LifePort™ perfusion pumps are taken to the Main Operating Room Control Desk. The CSC will arrange transportation of the pumps to the designated hospital(s). The SRC may be asked to transport the pump from the Ottawa Civic to the Ottawa General if required.

58. In cases where a kidney will be transported to a designated hospital unaccompanied by an SRC using a transportation service or OPP, the SRC will affix a tamper proof indicator to the pump

Post Recovery

59. If the kidney is deemed to be unsuitable for transplant post recovery TOH quarantines the kidney in their designated area in the OR and immediately contacts the PRC for further direction.

60. The LifePort™ is cleaned after the kidney transplant by TOH OR staff. TOH staff only return cleaned pumps to the OR.

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 Recipient Transplant Operating Room Data	CSF-9-52	PRC	PRC	16 years
Organ Donor Surgery Information	CSF-9-57	PRC	PRC	16 years

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Kidney Retrieval Operative Note	CSF-9-53	PRC	PRC	16 years
Kidney DCD Retrieval Operative Note	CSF-9-51	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*
- *Perfusion & Packaging: Kidney Perfusion with LifePort Pump, CPI-9-414*
- *Coordination and Recovery of Adjunct Vessels for use in Solid Organ Transplants, CPI-9-1007*

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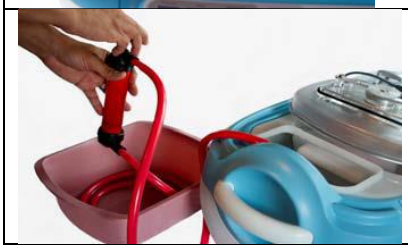
Appendix 1: Process for adding ice to LifePort™ during operation

	**Step 1** With Lifeport™ in operation it may be necessary to remove water and add ice to maintain a temperature below 8°C.
	**Step 2** Remove the lid. No need to stop or pause perfusion. This is NOT a sterile procedure.
	**Step 3** With the lid removed, you must now remove the water to allow room for more ice. The ideal ice to water ratio is 4.5 kg to 0.5 L (10 lbs. to 0.5 L)
	**Step 4** Remove the water with a manual pump shown here, or a cup, or a scoop.

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	**Step 5** When the water is drained, add as much ice as possible ensuring the water level is at the top of the ice container and is at the recommended ice to water ratio.
	**Step 6** Replace the lid being careful not to disturb the cassette.
	**Step 7** Lock the ice container lid. Replace outer Lifeport™ lid and continue to monitor temperature hourly.