Ontario
Trillium Gift of Life Network

Clinical Process Instruction Manual

Perfusion & Packaging: Heart 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.

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 Retrieval Operative Note.* See Exhibit 1.
    - *Heart Recipient Transplant Operating Room Data* with attached ABO and Serology. See Exhibit 2.
    - *HLA Lab Requisition Form*
    - *Laboratory Services Requisition: STAT/NON-STAT Infectious Disease Testing of Organ Donors* (if required)
    - *Public Health Requisition* from Public Health (if required)
    - Organ Labels
    - Specimen Labels
    - Surgical supply list (if needed)

    For organ recoveries performed by transplant programs, the *Organ Donor Surgery Information* and the *Heart Recipient 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 heart surgical recovery kit. The SRC reviews the contents of the kit to ensure that all required supplies are present:
    - 2 sets of sterile perfusion tubing
    - 2 portal cannula

- 2 1000ml jar
- 3 pressure bags
- 3 tourniquet kits
- 6 Organ bags
- 3 aortic root cannula, 12GA
- 2 paediatric aortic root cannula 18GA
- 2 red top tubes
- 2 purple top tubes
- 4 yellow top tubes
- 3 pour spouts
- 2 specimen containers (non-sterile)
- 10 specimen bags
- hammer (to break up slush if needed)
- plastic lock
- sterile chest retractor (if not provided at the recovery facility)
- 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 regarding their integrity and places these supplies in a designated area of the surgical supply room.

4. The SRC obtains a red styrofoam cooler from the TGLN surgical supply room and lines it with a yellow plastic bag. The SRC then places the following items inside:
    - wet ice (fill 1/3 of the cooler)
    - 4 to 5 liters of Servator H for adult donor* or 3 bags of Servator H if using the OCS™ HEART machine
    - bottle of Tis-U-Sol for paediatric donor
    - 3 to 4 bags of frozen saline (sterile slush)

    *NOTE: Hospital for Sick Children will provide Cardioplegia for paediatric donors

    The SRC may obtain an additional small cooler for any extra, unused perfusion supplies that may require refrigeration after recovery.

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

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Departing TGLN

6. The SRC picks up the recovery team at a predetermined time and location. If it is a multi-organ donor and the OCS™ HEART machine is being used, one SRC will be responsible for the vehicle packed with the other recovery team and supplies, and the 2nd SRC will be responsible for transport of the OCS™ HEART machine, heart supplies and accompanying team members. The University Health Network (UHN) Heart Recovery Team will be responsible for all supplies required to operate the OCS™ HEART machine. The 2nd SRC will meet the UHN Heart Recovery team at the predetermined time and location and will assist with loading of the OCS™ HEART machine into the vehicle. The SRC should allow for an additional 30 minutes to load the OCS™ HEART machine for transport at the time of pick up.

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 Operating Room (OR) staff.

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

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

12. The SRC asks the OR staff for an intravenous (IV) pole for use during perfusion, a large basin and an extra table for heart packaging.

13. If the OCS™ HEART machine is being used, the SRC requests an additional back table and IV pole, in close proximity to a power source. The UHN Heart Recover Team ensures the OCS™ HEART machine is plugged in during the organ recovery in the donor OR. See Exhibit 3

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14. Prior to use, the frozen saline must be broken up into a slush-like consistency. The sterile slush is positioned within reach of the surgical team for organ cooling post cross clamp.

15. The SRC scrubs in and prepares the back table with the assistance of the circulating nurse. See Figure 1. The following materials are required:
    - 1 sterile basin
    - 1 – 2L of slush
    - 1 – 1000ml jar
    - 2 CardioMed organ bags
    - 1 small sterile specimen container
    - 1 2L normal saline (NS), as required by surgeon

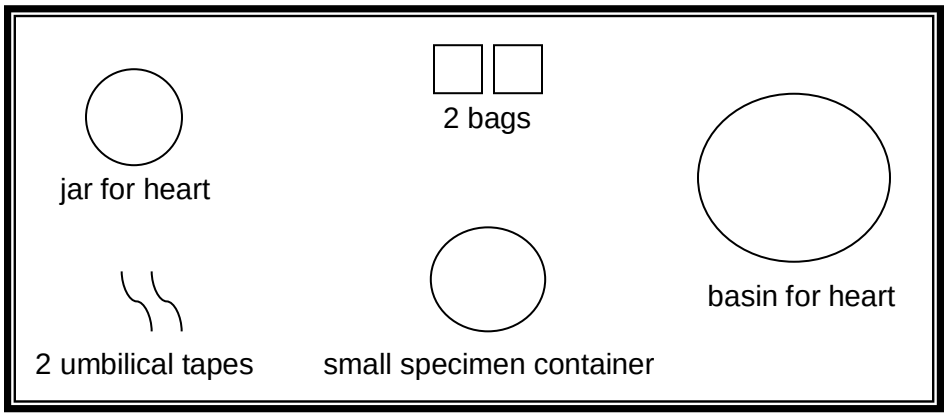

Figure 1: Sterile Back Table Set-up for Heart

16. The SRC places 1 bag of slush and 1-2L normal saline (NS) in the basin for the surgeon to use when rinshing the heart.

17. The SRC places 1 small sterile specimen container on back table for HLA spleen.

18. The SRC places 2 CardioMed bags with their associated 2 umbilical tapes on the back table.

19. A sterile perfusion line is positioned such that the cannula end of the tubing is asceptically secured onto the head of the OR table. The remainder of the tubing including the control clamp is secured outside the sterile field attached to a IV pole for SRC control.

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20. Once the setup of the back table is complete and perfusion line in place, the SRC scrubs out.

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. Prior to cross-clamp, the SRC opens the portal cannula, tourniquet and either an adult or paediatric aortic root cannula, which is to be determined by the cardiac surgeon to the scrub nurse to place on the scrub table.

23. After the surgeon has assessed the donor heart, the SRC notifies the CSC and provides an estimated time for aortic cross-clamp and organ suitability.

24. The CSC contacts the transplant physician upon notification.

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

26. When cross-clamp is imminent the SRC hangs Servator C or Cardioplegia solution and flushes the tubing with assistance from the scrub nurse or surgical team. The cannula end of the tubing is secured to the head of the operating table.

27. The SRC uses 2 to 3 pressure cuffs to cover each of the bags of Cardioplegia or Servator C solution. The SRC adjusts the pressure based on the recovery surgeon's recommendation.

28. At cross-clamp, the SRC records the time and begins to perfuse one bag of solution. Upon completion of the first bag, subsequent bags are consecutively perfused to completion. For adult donors it is routine to perfuse 3L (3 bags) of solution, to be adjusted at the discretion of the recovery surgeon.

29. If the OCS™ HEART machine is being used, the UHN Heart Recovery Team will cannulate the donor to obtain blood required for perfusion of the heart on the OCS™ HEART machine.

    29.1. For Donation after Death Determination by Circulatory Criteria (DCC), the other organ recovery teams will wait until the following occurs:

        29.1.1. A rapid sternotomy is performed and the pericardium is opened.

29.1.2. The right atrium is opened and 1.2 to 1.5L of blood is rapidly drained from the donor immediately prior to the flush of the abdominal organs.

29.1.3. The lung team will re-intubate the donor and other organ recovery teams will start recovering organs as per usual protocol.

29.2. The UHN perfusionists will prepare the OCS™ HEART machine while the UHN heart surgeon recovers the heart.

30. The SRC records name and volume of perfusion solutions and the name of storage solutions on the *Organ Donor Surgery Information.*

31. The SRC notifies the CSC and provides cross-clamp time, organ suitability and the estimated time of departure.

32. The SRC fills the heart container on the back table with either Tis-U-Sol (paediatric donor), or Servator C (adult donor) using a pour spout. The recovered heart will be inserted into the large jar and lid tightly secured by the surgeon. If the OCS™ HEART machine is being used, the heart is prepared for placement on the OCS™ HEART machine by the UHN Heart Recovery team.

33. The jar is then placed into a CardioMed organ bag by the surgeon, with the top of the bag tied off and secured with umbilical tape.

34. The bagged jar is then placed into a 2nd CardioMed bag by the surgeon and the top of the bag is folded over to secure it, maintaining aseptic technique.

35. The SRC obtains a splenic/lymph node sample from the surgical staff and it is placed in a small sterile specimen container filled with Tis-U-Sol or normal saline or perfusate. 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*.

36. The SRC labels the heart. See *Organ and Composite Tissue Labelling Process Instruction, CPI-9-417.* If the OCS™ HEART machine is being used, the SRC places the inner label directly on the circuit and the outer label is placed on the outside of the OCS™ HEART machine device container.

37. The organ bag is placed into a cooler and covered with ice.

38. If unaccompanied by a member of the recovery team to the recipient OR, the SRC secures the red styrofoam cooler 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

39. A copy of the *Heart Retrieval Operative Note* is completed, signed by the appropriate surgical staff and left in the hospital donor chart.

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

41. The SRC ensures all the labels are completed appropriately.

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

43. The SRC notifies the CSC and provides a report of any abnormalities or comments previously reported, as well as their time of departure.

Post Recovery

44. Upon arrival at the transplanting hospital, if the SRC is delivering the organ to the appropriate OR staff, the SRC signs the reverse of the cooler sheet with date/time.

45. The SRC ensures that donor blood, spleen, etc. samples are dropped off at the appropriate locations as per *Infectious Disease Testing – STAT Process Instruction, CPI-9-211* and *Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213.*

46. 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.

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

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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
Heart Retrieval Operative Note	CSF-9-38	Donor Hospital	Donor Hospital	16 years
Heart Transplant Operating Room Data	CSF-9-37	PRC	PRC	16 years
HLA Lab Requisition Form	CSF-9-23	PRC	PRC	16 years

References:

- Infectious Disease Testing – STAT Process Instruction, CPI-9-211
- Infectious Disease Testing – Non-STAT Process Instruction, CPI-9-213
- Clinical Services Coordinator to Surgical Recovery Coordinator Communication Process Instruction, CPI-9-406
- Organ and Composite Tissue Labelling Process Instruction, CPI-9-417
- Tissue Recovery Process Instruction, CPI-9-507
- Sterilization of Equipment – Organ Process Instruction, CPI-9-708
- Basic Safety Requirements for Human Cells, Tissues and Organs for Transplantation. Requirements, Guidance Document, Health Canada, July 2005

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Exhibit 1: Heart Retrieval Operative Note

CSF-9-38

UNIVERSITY OF TORONTO HEART TRANSPLANT PROGRAM

HEART RETRIEVAL OPERATIVE NOTE

Hospital: _____ Date: _____

Patient Name: _____ Medical Record Number: _____

Surgeons: _____

The heart was exposed through a median sternotomy and pericardiotomy. It was assessed clinically for function and presence of atherosclerotic disease in the coronary arteries. The superior vena cava was dissected above the azygos vein. The pulmonary artery was dissected off the aorta to make room for an aortic cross clamp.

Just prior to arrest of the donor heart, a cardioplegia cannula was placed in the ascending aorta. In coordination with other retrieval teams, and after heparin was administered to the donor, the superior vena cava was tied and the heart was arrested by cross-clamping the ascending aorta and infusing three litres of cold Servator C cardioplegia solution into the aortic root. The heart decompressed through an incision in the inferior vena cava above the diaphragm, as well as an incision in either the left pulmonary vein or in the left atrial appendage. Following arrest of the heart, it was excised completely and placed into a jar containing cold Servator C cardioplegia solution where it was examined further for any abnormalities. The jar was then placed into two sterile bags, each tied individually, and was then placed into a cooler full of ice for transportation.

ADDITIONAL NOTES

Hemodynamic Abnormalities: _____

_____

_____

Anatomical Abnormalities: _____

_____

_____

Other: _____

_____

_____

Signature: _____

March 29, 2023

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Exhibit 2: Heart Transplant Operating Room Data

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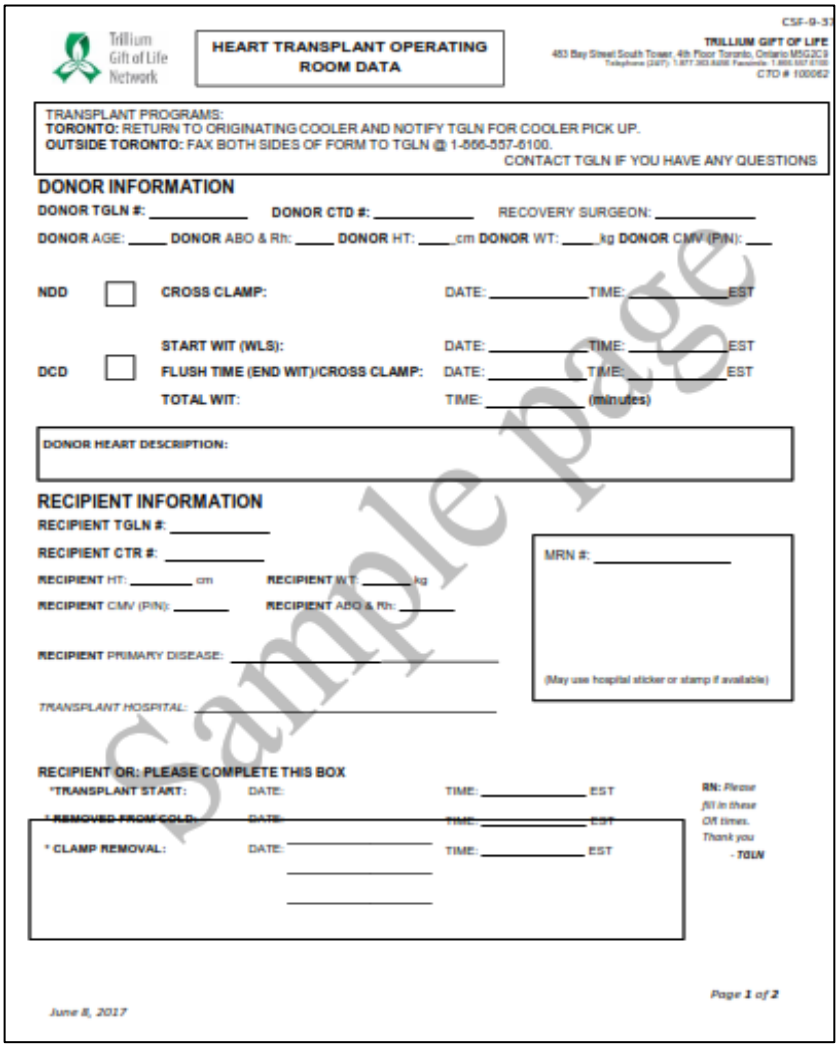

CSF-9-33

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HEART TRANSPLANT OPERATING ROOM DATA

TRILLIUM GIFT OF LIFE
483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G2C9
Telephone (24/7): 1.877.363.8458 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 #:** _____ 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 HEART DESCRIPTION:

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 START:** DATE: TIME: _____ EST
~~*** REMOVED FROM COLD:** DATE: TIME: _____ EST~~
*** CLAMP REMOVAL:** DATE: _____ TIME: _____ EST

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

June 8, 2017

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Exhibit 3: Insert OR Setup for DCC Heart Organ Recovery (potential placement)