Clinical Process Instruction Manual

Re-allocation, Re-packaging and Re-labelling Organs Process Instruction

Policy:

For recovery procedures where Trillium Gift of Life Network (TGLN) provides surgical recovery support, TGLN's Surgical Recovery Coordinator (SRC) 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 where TGLN is not providing surgical recovery support, a transplant program SRC designate undertakes surgical recovery activities including perfusion and packaging**.**

TGLN re-allocates organs declined by transplant programs in the donor operating room (OR) when appropriate (i.e., recipient medically unsuitable, atypical organ anatomy). TGLN will also attempt to re-allocate organs declined by transplant programs in the recipient OR. If the organ is successfully re-allocated to another transplant program, the transplant program in possession of the organ will be responsible for re-packaging and re-labelling the organ in accordance with the TGLN approved standardized process.

TGLN reviews all cases where the TGLN approved process was not followed and resulted in the organ being unsuitable for transplantation.

Process:

Re-allocation of organs in the donor OR

1. In the event an organ is declined in the donor OR, the SRC or designate will immediately telephone the Provincial Resource Centre (PRC) to notify the Clinical Services Coordinator (CSC).

2. The CSC will document the detailed reason for decline in the donor chart including the specifics relating to any anatomical abnormalities, surgical injury, or other relevant comments provided by the surgical recovery team.

3. If the organ is suitable for transplantation (i.e., recipient medically unsuitable, atypical organ anatomy, minor surgical damage, etc.), the CSC will communicate the need for organ re-allocation to the SRC or designate. If the organ has been declined for an organ quality related issue (i.e. poor perfusion, severe atherosclerosis, etc.), it does not need to be reallocated.

4. The SRC or designate will relay the plan to re-allocate the organ to the recovery teams in the donor OR.

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5. When an organ re-allocation will delay cross clamp in an NDD recovery:

   5.1. The SRC or designate will notify the CSC of any concerns from transplant recovery teams regarding the delay.

   5.2. The CSC will coordinate a rapid conference call between the recovery surgeon and all potential recipient program physicians to expedite the organ re-allocation and to allow for a detailed communication of organ suitability findings from the donor OR. The CSC will also make arrangements to share images (if requested) to help determine organ suitability.

   5.3. The Chief Medical Officer (CMO) –Transplant will be consulted as indicated if there is a request to go off allocation.

6. When organ re-allocation will not delay cross clamp, the CSC will make organ offers as per organ allocation algorithms to the next recipient program. The CSC will communicate the reason for the donor intra-operative organ decline and will convey the decision to accept or decline is time-sensitive.

7. If the organ is accepted, the CSC will generate an updated organ cooler sheet and notify the SRC or designate who will ensure the organ cooler paperwork is updated.

8. If a kidney is injured during recovery and the recovery program has been allocated a kidney, the recovery team will retain the damaged kidney, regardless of whether it is the left or right kidney. If the recovery team is not retaining the injured kidney, they will notify TGLN immediately and the CSC will arrange a telephone call between the recovery surgeon and the recipient surgeon(s) to discuss the details of the organ injury. Organs that are declined as a result of surgical injury will be re-allocated.

Re-allocation of organs in the recipient OR

9. In the event an organ is declined in the recipient OR, the transplant program will immediately telephone the PRC to notify the CSC.

10. The CSC will document the detailed reason for decline in the donor chart including the specifics relating to anatomical abnormalities, surgical injury, or other relevant comments provided by the receiving transplant program surgeon.

11. The CSC will explore the conditions under which the organ was open in the recipient OR (i.e., recipient present, location of organ and proximity to the recipient when opened). The CSC will document this information in the donor chart.

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12. The CSC will communicate the organ re-allocation process and plan to the recipient program and will ask that the organ be re-packaged and re-labelled. The CSC will fax a copy of the condensed version of the TGLN Packaging and labelling CPIs for Liver, Pancreas and Kidneys to the recipient OR. See Exhibit 1: *TGLN Re-packaging and Re-labelling Instructions*.

13. The CSC will review the organ allocation and proceed to offer the organ to the next recipient on the allocation.

14. The CSC will apply Exceptional Distribution (ExD) to organs being re-offered after being declined in the recipient OR that have been re-packaged and labelled by anyone other than a TGLN SRC or designate as per *CPI-9-217 – Exceptional Distribution.*

15. When re-offering, the CSC will communicate the reason for organ decline in the recipient OR, reason for ExD, as well as any information gathered in process step #11. The CSC will convey the decision to accept or decline is time-sensitive.

16. TGLN will facilitate a conversation with the surgeon from the transplant program in possession of the recovered organ (if requested) and will also make arrangements to share images (if requested) to help determine organ suitability.

17. If the organ is accepted, the CSC will generate an updated organ cooler sheet, and *Notice of Exceptional Distribution* form and sends them via fax to the transplant program in possession of the recovered organ.

18. The CSC will make the necessary transportation arrangements for delivery of the re-allocated organ.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)

- No records

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References:

- *CPI-9-409, Perfusion & Packaging: Liver*
- *CPI-9-412, Perfusion & Packaging: Whole Pancreas, Kidney-Pancreas and/or Pancreas for Islets*
- *CPI-9-413, Perfusion & Packaging: Kidney without LifePort Pump*
- *CPI-9-414, Perfusion & Packaging: Kidney Perfusion with LifePort Pump*
- *CPI-9-429, Perfusion & Packaging: Kidney Perfusion with LifePort Pump - Eastern*

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Exhibit 1: Re-packaging and Re-labelling Instructions for Liver, Pancreas & Kidneys

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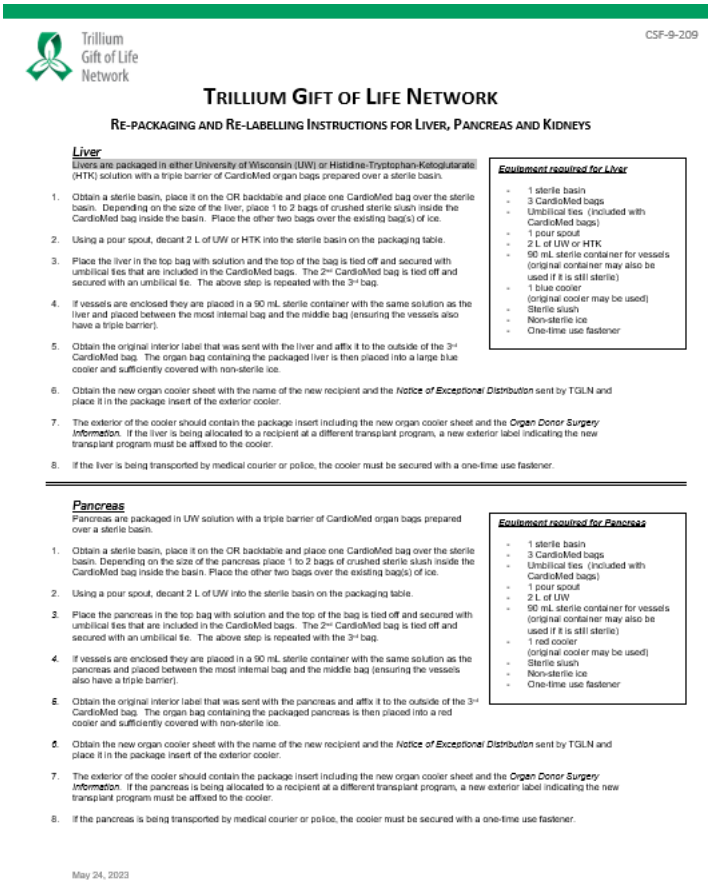

Trillium Gift of Life Network

CSF-9-209

TRILLIUM GIFT OF LIFE NETWORK

RE-PACKAGING AND RE-LABELLING INSTRUCTIONS FOR LIVER, PANCREAS AND KIDNEYS

Liver

Livers are packaged in either University of Wisconsin (UW) or Histidine-Tryptophan-Ketoglutarate (HTK) solution with a triple barrier of CardioMed organ bags prepared over a sterile basin.

Equipment required for Liver

- 1 sterile basin
- 3 CardioMed bags
- Umbilical ties (included with CardioMed bags)
- 1 pour spout
- 2 L of UW or HTK
- 90 mL sterile container for vessels (original container may also be used if it is still sterile)
- 1 blue cooler (original cooler may be used)
- Sterile slush
- Non-sterile ice
- One-time use fastener

1. Obtain a sterile basin, place it on the OR backtable and place one CardioMed bag over the sterile basin. Depending on the size of the liver, place 1 to 2 bags of crushed sterile slush inside the CardioMed bag inside the basin. Place the other two bags over the existing bag(s) of ice.
2. Using a pour spout, decant 2 L of UW or HTK into the sterile basin on the packaging table.
3. Place the liver in the top bag with solution and the top of the bag is tied off and secured with umbilical ties that are included in the CardioMed bags. The 2nd CardioMed bag is tied off and secured with an umbilical tie. The above step is repeated with the 3rd bag.
4. If vessels are enclosed they are placed in a 90 mL sterile container with the same solution as the liver and placed between the most internal bag and the middle bag (ensuring the vessels also have a triple barrier).
5. Obtain the original interior label that was sent with the liver and affix it to the outside of the 3rd CardioMed bag. The organ bag containing the packaged liver is then placed into a large blue cooler and sufficiently covered with non-sterile ice.
6. Obtain the new organ cooler sheet with the name of the new recipient and the *Notice of Exceptional Distribution* sent by TGLN and place it in the package insert of the exterior cooler.
7. The exterior of the cooler should contain the package insert including the new organ cooler sheet and the *Organ Donor Surgery Information*. If the liver is being allocated to a recipient at a different transplant program, a new exterior label indicating the new transplant program must be affixed to the cooler.
8. If the liver is being transported by medical courier or police, the cooler must be secured with a one-time use fastener.

Pancreas

Pancreas are packaged in UW solution with a triple barrier of CardioMed organ bags prepared over a sterile basin.

Equipment required for Pancreas

- 1 sterile basin
- 3 CardioMed bags
- Umbilical ties (included with CardioMed bags)
- 1 pour spout
- 2 L of UW
- 90 mL sterile container for vessels (original container may also be used if it is still sterile)
- 1 red cooler (original cooler may be used)
- Sterile slush
- Non-sterile ice
- One-time use fastener

1. Obtain a sterile basin, place it on the OR backtable and place one CardioMed bag over the sterile basin. Depending on the size of the pancreas place 1 to 2 bags of crushed sterile slush inside the CardioMed bag inside the basin. Place the other two bags over the existing bag(s) of ice.
2. Using a pour spout, decant 2 L of UW into the sterile basin on the packaging table.
3. Place the pancreas in the top bag with solution and the top of the bag is tied off and secured with umbilical ties that are included in the CardioMed bags. The 2nd CardioMed bag is tied off and secured with an umbilical tie. The above step is repeated with the 3rd bag.
4. If vessels are enclosed they are placed in a 90 mL sterile container with the same solution as the pancreas and placed between the most internal bag and the middle bag (ensuring the vessels also have a triple barrier).
5. Obtain the original interior label that was sent with the pancreas and affix it to the outside of the 3rd CardioMed bag. The organ bag containing the packaged pancreas is then placed into a red cooler and sufficiently covered with non-sterile ice.
6. Obtain the new organ cooler sheet with the name of the new recipient and the *Notice of Exceptional Distribution* sent by TGLN and place it in the package insert of the exterior cooler.
7. The exterior of the cooler should contain the package insert including the new organ cooler sheet and the *Organ Donor Surgery Information*. If the pancreas is being allocated to a recipient at a different transplant program, a new exterior label indicating the new transplant program must be affixed to the cooler.
8. If the pancreas is being transported by medical courier or police, the cooler must be secured with a one-time use fastener.

May 24, 2023