Clinical Process Instruction Manual

Organ Cooler Usage and Validation Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) uses coolers to transport recovered organs from a recovery hospital to a transplant hospital. The coolers serve as a means for storage and transportation of human organs and tissues by TGLN.

Process:

1. All organs recovered are stored in designated coolers.

2. The Manager, Surgical Recovery Services - Organ or designate is responsible for informing the Quality Department when new designated coolers are to be introduced. These coolers will be validated prior to usage either by TGLN or the Transplant Program providing the cooler. Only new coolers with changes in dimensions greater than 10% require testing. For example, if a new cooler has a less than 10% change in volume or wall thickness from an existing validated cooler, validation is not required. Changes in non-cooling abilities (e.g. an increase or decrease in cupholders, wheels, handles, colour change, etc.) will not require validation to occur.

3. Sterility is maintained in storage and transportation through a combination of organ bags and organ jars. The coolers protect the organs from any environmental factors.

4. Designated coolers maintain temperature and safety throughout the interim storage and transportation processes.

5. Coolers are secured to maintain safety of organ at all times during transport.

6. Coolers are transported through a variety of means including TGLN van, courier, Ontario Provincial Police, road ambulance, air ambulance and Air Canada medical desk.

7. In the case of an organ being quarantined, the cooler provides this quarantining function, without any additional segregation or special facility/ room requirement.

8. Once the cooler is cleaned, the SRC places a green “I am clean” sticker on the cooler. See Exhibit

9. Once every five years, TGLN or the Transplant Program validates as a minimum one of each cooler type to ensure that each one is capable of maintaining temperature requirements of greater than 0°C to 10°C or alternative scientifically determined suitable temperature range.

10. Organs under transport could be exposed to extreme environments that are different from the conditions present at the time of validation and as a result there may be a concern to the viability of the organ. This will require clinical judgement based on the insulating properties of the device, exposure time and external environmental conditions. When an event under these extreme conditions occurs, the transplant surgeons or designate will contact the CSC to consider exceptional distribution if required and/or possible.

TGLN Validation Process

11. A random sampling of each cooler type is employed to verify the coolers ability to maintain temperatures between 0° to 10°C for a mimimum of 24-hours shall be conducted upon introduction under normal office conditions and externally under winter and summer conditions in triplicate (either three of each type of cooler or where three of each type of cooler doesn't exist, the same cooler will be tested three times) as soon as it is realistically possible to do so. In order to avoid any impact to OH-TGLN's ability to recover organs, a cooler type may be tested over a 2 week period with weather conditions averaged over the test period. A record of this activity will be maintained by the Quality Systems Department. Data from previous testing may be used to validate the coolers.

12. The following materials are required for performing a validation of each cooler type (cooler types tested will be documented in the validation report):

- Coolers
    - Yellow cooler liner bag;
    - NIST Traceable Calibrated Egg Temperature Monitoring Data Loggers;
    - Cold tap water;
    - CardioMed Organ bags;
    - 3M Steri-drape bags;
    - Specimen Jar;
    - Non-sterile ice.

13. Thermometers are initially tested beforehand to ensure functionality.

14. Cooler is set up as follows:

    14.1 Lined the cooler with a yellow liner bag

14.2 Fill the cooler 1/2 of the way with ice

14.3 Place temperature monitoring egg (this simulates a human organ)

14.4 Fill the jar with cold water

14.5 Seal the jar

14.6 Place jar into 2 CardioMed bags, ensuring all air is expelled from them

14.7 Tie each bag off individually (inner bag and then outer bag)

14.8 Place package in depression created in the ice such that only 2 inches of the organ jar is uncovered by the ice. (See Figure 1)

14.9 Close the cooler.

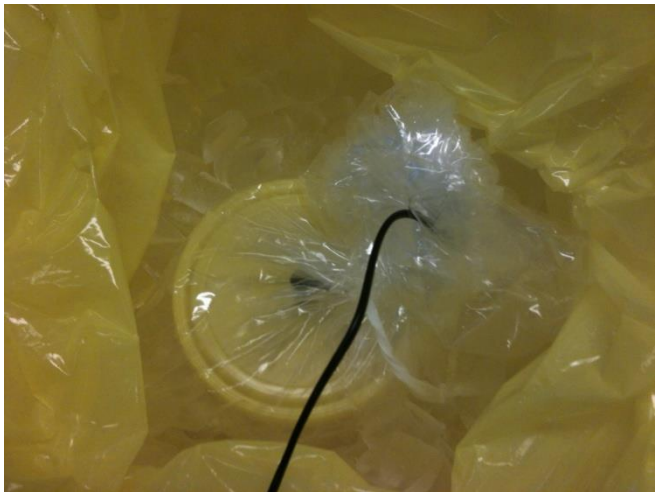

Figure 1: Bagged organ container in a Red Foam Cooler

15. All other coolers are set up as follows:

15.1 Fill the cooler such that 50% of the volume is ice.

15.2 Place equivalent temperature monitoring egg in a 3M Steri-drape/CardioMed bag with the temperature probe (this represents the human organ).

15.3 Fill bag with 1.5 litres of cold water.

15.4 Expel all the air from the bag prior to tying it off.

15.5 Place this bag into another 3M Steri-drape/CardioMed bag and also ensure all air expelled from it prior to being tied off.

15.6 Place the first two bags into this bag, again ensuring all air is expelled prior to tying the bag off.

15.7 Create a depression in the ice to accommodate the bags.

15.8 Once placed on top of the ice, gently push ice over the top of the bag. Ensure that approximately 2/3 of the top of the bag is left uncovered (as shown in Figure 2).

15.9 Close the cooler.

Figure 2: Organ bags sitting on and surrounded by ice

16. Allow the Egg Data Logger to run for at least 10 minutes prior to starting the setup of the test to measure ambient temperature.

17. After at least 24 hours, retrieve the Egg Data Logger to download the data.

18. Evaluate results and issue *Validation of Coolers Used for Transporting Human Organs* report to the Quality Director for review once complete.

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Transplant Program Validation Process

19. Transplant programs may use and validate their own coolers. TGLN requires them to perform a validation at least once every five years and provide their report to TGLN for review and approval.

Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Validation of Coolers Used for Transporting Human Organs Report	——	Quality Assurance Department	Quality Assurance Department	16 years
Transplant Program Validation Report	——	Transplant Program	Transplant Program	16 years

References:

- Z900.2.3 Perfusable Organs for Transplantation CSA Standard.

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Exhibit 1: Disinfection Label

CSF-9-61

I am clean

☐

Date _____/_____/_____

Time _____ am/pm

Name _____

Please remove before using equipment

clinell® clean

June 19, 2018