Ontario Health
Trillium Gift of Life Network

Clinical Process Instruction Manual

Sterilization of Equipment – Tissue Process Instruction

Policy:

Trillium Gift of Life Network (TGLN) ensures that all tissue recovery instruments have been properly cleaned, disinfected and sterilized between tissue recovery cases to prevent infectious disease contamination or cross-contamination by tissues.

TGLN has contracted an external agency which specializes and provides sterilization services for hospitals and health care facilities. This process applies to all re-usable surgical equipment and instruments used by TGLN. Instruments are sterilized based on manufacturer's recommendations and applicable industry standards.

TGLN maintains records indicating that tissue recovery instruments have been sterilized. For traceability, the sterilization agency will provide a copy of the lot record to TGLN upon request. TGLN will retain documentation of sterilization lot numbers in the donor chart and documents receipt, acceptability, and load information on the *Equipment Sterilization Log*.

Process:

General

1. Applicable instruments used for tissue recovery must be decontaminated and sterilized after each use.

2. Protective apparel, including protective clothing, eye protection, and gloves, shall be worn while handling equipment and instruments that has been used during tissue recovery. Refer to *Routine Practices and Personal Protective Equipment Process Instruction, CPI-9-1504.*

Post Recovery

3. Upon return to the TGLN office, used equipment and instruments shall be taken to the utility room. At the OFPS the used instruments shall be placed in containers in the designated area.

4. The Tissue Recovery Coordinator (TRC) or Multi Tissue Recovery Coordinator (MTRC) will ensure all equipment and instruments are placed into the appropriate tray.

5. Used trays will be wrapped in a large clear plastic bag and labelled with a "Used Medical Device" sticker.

6. The dirty trays will then be transferred to the used instrument plastic tote/bin. Attach a "Used Medical Device" red sticker label, complete the equipment sterilization log and arrange for tray pick-up.

7. The (M)TRC completes the *Equipment Sterilization Log*. See Exhibit 1. Documentation includes:
   - item name and number
   - date
   - staff initials

8. Transportation to the sterilization facility is arranged on an as needed, basis.

Post Sterilization

9. Upon return to TGLN, the inventory staff or designate shall inspect the equipment / instrument tray to ensure the wrapping is intact, that there is a load number, and verifies that the sterilization has occurred. Discrepancies should be reported to the clinical specialist and Inventory staff who will contact the sterilization facility.

10. The inventory staff or designate shall complete the *Equipment Sterilization Log*. Documentation includes:
    - date received
    - load number
    - name and signature of the staff verifying acceptability of sterilization and release of the tray into inventory.

11. Sterile equipment and instruments shall be placed into the Multi Tissue Room at Bay street and the supply room at the OFPS for use in subsequent cases.

12. Expiry dates are event related and packages are considered sterile until they are opened or until an event occurs that may compromise integrity of the exterior wrap.

13. An audit of sterilization logs and records from the sterilization facility are performed annually and approved by Quality.

Identification, Quarantine and Destruction of Contaminated Tissue Recovery Trays

14. Upon notification of known or suspected prion-associated disease in a donor that TGLN has recovered, the (M)TRC or designate obtains the TGLN number and references the 'Supply List' tab of the 'Tissue Recovery' section in Donor Management System (DMS) to determine whether a reusable instrument set was used. If so, the (M)TRC or designate obtains the tray and load numbers. Then notification must occur to the Manager or designate and Quality in writing on the same shift in which the incident was reported.

15. (M)TRC or designate refers to the Sterilization Log to identify whether the affected recovery tray is located in the supply room or if it is with the sterilization service provider.

16. If the exposed tray is in the supply room, the (M)TRC or designate identifies, isolates and quarantines the tray.

17. If the exposed tray is currently undergoing sterilization, the (M)TRC or designate contacts the sterilization provider and provides them with the ID number of the exposed tray and requests for the tray to be identified, isolated and quarantined. The (M)TRC or designate is required to pick up the quarantined tray from the sterilization service provider. Documentation of the notification of the sterilization service provider shall be documented in the donor chart in addition to being provided to the Manager and Quality.

18. Once the tray is in TGLN's possession, it must be taken out of circulation and quarantined until confirmation of a prion-associated disease is obtained.

19. (M)TRC or designate shall notify affected stakeholders including Quality, tissue banks receiving tissue from the affected donor, processors and recovery personnel of the status of the donor and instrument tray on the same shift in which the occurrence happened.

20. Upon confirmation of a prion-associated disease, the tissue recovery trays will be destroyed as per instructions from the Manager or designate. All affected stakeholders will be informed of the CJD confirmation and outcome.

21. Upon confirmation of a negative prion-associated disease test result, the Manager or designate will release the affected tissue recovery tray(s) from quarantine and the tray(s) will be sent to the sterilization service provider for sterilization. The (M)TRC or designate on shift will inform all affected stakeholders of the negative test result.

22. Wherever possible, the (M)TRC or designate shall obtain copies of the test results, upload copies to the donor chart and share them with stakeholders involved as appropriate.

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Equipment Sterilization Log	CSF-9-84	Tissue Department	Tissue Department	16 years

References:

- V. Mueller Products and Services – General Surgical Instrument Sterilization Guide
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D5.100, D5.500
- *Universal Precautions and Personal Protective Equipment Process Instruction, CPI-9-1504.*

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Exhibit 1: Equipment Sterilization Log

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CSF-9-84

Equipment Sterilization Log

Item and ID Name	Date Used dd/mmm/yyyy	Used by (Initials)	Date Of Receipt dd/mmm/yyyy	Load Number	Inspected and Released Into Inventory for Use (initial/date) dd/mmm/yyyy