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Clinical Process Instruction Manual

Multi-Tissue Recovery Environment and Preparation Process Instruction

Policy:

All tissues shall be recovered in an aseptic fashion using standard surgical preparation with sterile packs, instrumentation, and technique.

All recoveries shall be conducted in an operating room or other approved recovery suite, such as the Ontario Forensic Pathology Services (OFPS) Medical Tissue Recovery Suite, using pre-established criteria designed to control contamination and cross-contamination.

All working surfaces used for recovery shall be cleaned with a bactericidal and/or antimicrobial agent, in accordance with *American Association of Tissue Banks* (AATB) Current Standards for Tissue Banking and Health Canada requirements, and are to be maintained and monitored by each individual hospital operating room (OR) and by the OFPS.

Documentation may be requested from any facility in which Trillium Gift of Life (TGLN) recovers tissue regarding the verification records of the cleaning and sanitization of the OR prior to recovery.

The location of the recovery (at any site) and verbal verification of OR suitability OR staff (if the recovery takes place in a hospital OR), prior to the start of recovery activities, shall be recorded in the donor chart.

Surgical suites in hospitals shall be clean before the start of a case. The room, bed and tables will be clean, prepared, and ready for use.

An evaluation of the recovery site shall be performed to identify potential sources of contamination. The evaluation must address the control of: size/space; lighting; plumbing and drainage for the intended use; the physical state of the facility (i.e., state of repair); ventilation; cleanliness of room and furniture surfaces; pests; traffic; location; other activities occurring simultaneously; sources of contamination and; ability to appropriately dispose of biohazardous waste and handle contaminated equipment

If the recovery environment does not meet the requirements, then arrangements to access another OR shall be made directly with the facility or additional cleaning of the OFPS Medical Tissue Recovery Suite will be performed until adequate conditions have been achieved. If a suitable recovery environment cannot be achieved, recovery shall not proceed.

At the OFPS, all working surfaces used during recovery shall be disinfected using a bactericidal/antimicrobial agent prior to and after recovery activities have been completed. All cleansing and disinfection events performed by the recovery agency shall be documented on the OFPS Medical Tissue Recovery Suite Cleaning Log, located in the recovery suite. Cleaning supplies are provided and regularly replenished.



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Process:

Hospital Operating Rooms Environment

- 1. Upon arrival on site, confirm suitability of the OR suite with OR staff and document in the donor chart.
- 2. The site inspection shall be performed and document in the donor chart.
- 3. If, after inspection, the OR does not meet the required environmental conditions, request an alternate OR or identify deficiencies and share with hospital staff to remedy the issue(s). If the requirements cannot be achieved, tissue recovery shall not proceed.
- 4. Upon completion of recovery, OR staff shall be notified to allow appropriate environmental cleaning to take place.

OFPS Medical Tissue Recovery Suite Environment

- 5. Terminal cleaning of the recovery suite is performed on a routine basis (weekly) by the OFPS as documented in the on-site cleaning records.
- 6. Prior to each tissue recovery, recovery personnel shall use the disinfectant wipes provided to wipe down all work surfaces, including but not limited to, the overhead adjustable surgical light, the operating table, work tables, chairs, and counter tops.
- 7. The site inspection shall be performed and document in the donor record.
- 8. If the suite does not meet the required environmental conditions, and deficiencies cannot be corrected adequately, tissue recovery shall not proceed and the Tissue On Call will be notified via email for follow up.
- 9. Once the recovery is complete, the body, recovered tissue and garbage shall be removed prior to environmental cleaning.
- 10. The recovery personnel shall follow the cleaning instructions in CPI-9-553 Cleaning of Tissue Recovery Suite at Forensic Services & Coroner's Complex.



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Prior to Recovery Set Up

- 11. Recovery activities and set up of supplies and equipment shall not occur prior to completion of environmental cleaning and confirmation of acceptable results from the site inspection.
- 12. No one shall enter the recovery suite without proper attire as defined by the Surgical Attire and Conduct Process Instruction, CPI-9-523.
- 13. Expiration dates and package integrity shall be checked for all sterilized equipment, materials, and reagents/solutions prior to opening. Do not use any items that have expired or have compromised package integrity.
- 14. All lot numbers and expiry dates of consumables and instruments that will be used for recovery shall be recorded in the donor chart prior to recovery. In the event the donor chart is not accessible, the *Tissue Supply List* shall be completed and added to the chart. See Exhibit 1.
- 15. The supply list shall be reviewed prior to the recovery to ensure that none of the consumables and instruments is expired.
- 16. Do not use sterilized equipment, materials, and reagents/solutions if tears, wetness, broken seals, or overall damage is found.
- 17. All products marked as "For Single Use Only" shall be checked to ensure they have not been resterilized. Do not use any single use device that has been re-sterilized.
- 18. The external indicator shall be verified as having been exposed to sterilization for non-disposable supplies.
- 19. The sterilization lot number and date shall be verified on the outside of the sterile packaging for non-disposable supplies. If no date and lot number are on the packaging, do not use the sterile instrument/supply.
- 20. Proper traffic patterns should be followed when setting up a recovery site.



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Multi-Tissue Recovery Environment and Preparation Process Instruction

Lead Multi Tissue Recovery Coordinator Duties

21. When a donor is accepted for recovery, the Lead MTRC shall:

- 21.1 Organize a confirmed recovery time and location with the Provincial Resource Centre (PRC). PRC staff are responsible for booking and/or communicating operating room times at the recovery site;
- 21.2 Ensure that recovery supplies are packed and double checked from the supply list prior to the recovery and to ensure that none of the consumables and instruments is expired.
- 21.3 Review Consent, Coroner Permission form, referral and MSHx and other relevant forms prior to dispatching.
- 21.4 Ensure travel and/or transport arrangements are made to get to the hospital;
- 21.5 Proceed to the recovery site;
- 21.6 Complete or assign the pre-recovery medical records review and associated documentation;
- 21.7 Confirm the suitability of the recovery site and donor refrigeration time;
- 21.8 Oversee that the donor identification and physical examination was completed.

Multi Tissue Recovery Coordinator Duties

22. The MTRC shall arrive at TGLN or the OFPS no later than the time indicated by the PRC.

23. The MTRC may also meet the team at an agreed-upon location (e.g., hospital), however this is the exception and not the rule. Approval from the manager or on-call manager will be require

24. All members of the recovery team shall review the consent prior to starting the case as well as the coroner permission form, if applicable.

25. Recovery activities to be conducting include, but are not limited to:

- preparation of the recovery suite and donor
- chart review and physical assessment
- complete all other MTRC documentations within iTransplant
- surgical procedures for recovery
- donor reconstruction
- assisting with transport of the donor to and from the morgue
- assisting with any other recovery duties as identified by the Lead MTRC



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Set Up

26. Preparation of the sterile operating table is performed by the Lead MTRC or scrub MTRC and the second scrub MTRC, with assistance from the circulator. Only gowned and gloved personnel should touch the sterile table, kits and contents of the kits throughout the set up and recovery procedure. Only the circulator should touch non-sterile supplies and containers. This reduces the possibility of cross- contamination.

Skin

- 27. The interior clear plastic bag shall be opened along the dotted lines, remove the kit and place it on a large operating room table with the arrows pointing to the back of the table. The two indicators "Press Here" should face towards the long side of the table, while opening the kit, in order to cover the OR table accordingly.
- 28. The outer blue sheet wrapping the kit also doubles as the sterile OR table cover to create the sterile field, therefore follow ORNAC guidelines when opening it. Press on the dotted lines on the paper tape to open and spread the blue sheet over the table using aseptic technique. The packages inside contain all of the sterile materials required other than the solutions (i.e., OR gowns, towels, OR drapes, clips, forceps, jars, etc.).
- 29. The Lead MTRC or scrub MTRC and second scrub MTRC shall open the sterile packs and place the materials and instruments on the table.
- 30. Two sterile prep packs will need to be opened to perform the surgical preparation of the donor. The betadine and chlorhexidine solutions shall be placed on the table (outside of sterile field). The betadine solution will be poured in an aseptic manner into one of the sterile prep containers, the chlorhexidine will be poured using the same technique into the second sterile prep container.
- 312. A small basin for the chlorohexidine and normal saline and the 2 jars for Tis-U-Sol[®] Solution shall be placed close to the edge of the table so the circulator can pour the solutions in aseptically as required.
- 32. The circulator opens the sterile Amalgatome wrapping using aseptic technique and hands the Amalgatome case to the Lead MTRC/scrubbed MTRC or the second scrub MTRC.
- 33. The scrubbed MTRC ensures that all materials required for the recovery procedure are present on the table.



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Cardiac and Musculoskeletal

- 3. When required, remove the recovery pack from its peel pack/dust cover. Continue to open the pack as follows:
 - 3.1. The recovery pack shall be taken to the appropriate back table.
 - 3.2. The flaps of the recovery pack shall be opened aseptically.
 - 3.3. Sterile gloves shall be opened onto the sterile field with sterile gown.
- 35. The remaining sterile recovery pack shall be opened aseptically to cover the back table and expose the recovery supplies.
- 36. The Lead MTRC or scrub MTRC will set up instruments and materials on the back table after scrubbing, gowning and gloving.
- 37. As required, the circulator opens the instrument outer cases, using aseptic technique; and the Lead or scrub MTRC aseptically removes the inner sterile basket, containing the saw or instruments, and places them on the sterile table.
- 38. The scrub MTRC ensures that all materials required for the recovery procedure are present on the table.



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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Donor Chart		PRC	PRC	16 Years
Tissue Supply List	CSF-9-186	Tissue Department	Tissue Department	16 Years

References:

- Standards for Tissue Banking, American Association of Tissue Banks, United States. D5.500, D5.501, D5.510.
- AATB Guidance Document No.2
- Cleaning of PFPU Medical Tissue Recovery and Scrub Room P-PRO-PFPU-22.0
- ORNAC Standards
- Surgical Attire and Conduct Process Instruction, CPI-9-523



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Exhibit 1 Tissue Supply List

						C5F-9-18
0-Ont	ario					
Tilliam GP	t of Life Betwork					
					TOLN #:	
		1	Tissue Supp	ly Lint		
Supply	Manufacturer	Lot #	Load #	Sterilization Indicator Y / N	Expiry Date/Manufacturer Date/Sterilization	# of Units Used
70% Isopropyl Alcohol					Date	\mathbf{Z}_{λ}
Alcohol Wipes						
Amalgatome						
Amaigstome Blade						
Amaigatome Power Supply and Power Cord						
Antibiotic- Bacitracin						
Antibiotic-Streptomycin			1			
Avagard				\bigcirc	×	
Bactec Blood Culture		-				
Vial- Aerobic Bactec Blood Culture				1		
Vial- Anaerobic		AL				
Bag Decanter						
Basin, Stainless steel, Sterile Betadine						
Blood Draw Needles 16g		r				
Blood Draw Needles 18g	5					
Blood Draw Syringe 30ml						
Blood Draw Syringe 60ml						
Blood Tube, EDTA						
Blood Tube, Red Top						
Blood Tube, Tiger Top						
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