

THE UNIVERSITY OF CONNECTICUT HEALTH CENTER
JOHN DEMPSEY HOSPITAL
ADMINISTRATIVE MANUAL

SECTION: PATIENT CARE

NUMBER: 08-076

SUBJECT: TISSUE MANAGEMENT

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POLICY:

1. Overall authority, accountability and responsibility of the tissue management program at John Dempsey Hospital belong to the Tissue Management subcommittee of the OR Committee. Quality monitoring and maintenance of storage equipment belongs to Materials Management staff.

Reporting to the OR Committee will address, but not be limited to:

- a. tissue recall notices
 - b. adverse tissue reactions
 - c. organ procurement updates
 - d. follow-up from past issues
 - e. any other items of importance
2. Tissue is not harvested for allograft purposes except by agencies certified to do so. Materials Management will procure human tissue for implantation directly from the supplier. No human tissue will be accepted directly from a Health Care Industry representative.

In order to prevent disease transmission and help ensure optimum clinical performance of transplanted cells, tissue devices and tissue implants will be obtained preferentially from suppliers that meet standards established by the

- a. FDA
 - b. American Association of Tissue Banks (AATB); or
 - c. Eye Bank Association of America,
 - d. and from suppliers with ISO certification. Current listings of tissue banks that comply with AATB accreditation requirements may be accessed at <http://www.aatb.org/>.
3. Tissue devices and tissue implants will be considered high priority for attention upon delivery to the Health Center, and Materials Management staff will accept such items promptly. Materials Management staff will follow all guidelines established by the supplying tissue bank for care and handling of each specific tissue, as provided by the supplier.

As tissue is received, Materials Management staff will check it for:

- a. correct tissue type, as well as its specifications of ordering, including temperature within required range;
 - b. acceptance of the integrity of the shipping package such as evidence of contamination or tampering, or for evidence that the tissue was not maintained in its required environment during shipping;
 - c. acceptance of the shipping package by checking its posted expiration date / time, if applicable (for refrigerated, frozen, or cryopreserved allografts) or for eye tissue by checking for evidence that coolant is present;
 - d. that the accuracy of the labeling of each allograft was checked and that package inserts for each match the tissue type that was received; and
 - e. that each allograft's immediate container is intact.
4. Temperature sensors will be located in each location of tissue storage requiring temperature monitoring. The readings of these sensors are to be maintained by ECC.

Ambient temperatures will be logged by ECC on a log; temperature readings that fall outside the accepted values will be immediately reported to the staff in the location where the items are stored and steps will be taken to correct the temperature with appropriate follow-up to the affected patient care area.

The refrigerator(s) and freezer(s) used for storage of tissue are on plugs connected to the emergency power generator.

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5. Unless specified otherwise by the supplier:
 - a. Frozen cadaver bone will be stored in the designated freezer in the JDH OR inner core within the acceptable temperature range, approximately -80°C.
 - b. Tissue that must be stored in a temperature-controlled refrigerator (2° – 4° C.) will be stored in the designated area of the OR blood refrigerator. Materials Management and / or OR staff will contact the Blood Bank regarding storage of items too large for this designated space.
 - c. Freeze-dried tissue is stored at room temperature and reconstituted according to directions accompanying the tissue.

Tissue that must be stored in a temperature-controlled environment will be kept within acceptable temperature range, as identified by the tissue supplier, or it will be discarded. The Blood Bank will be the back-up storage location should the monitored refrigerator fail; the Tumor Bank freezer will be the back-up storage location should the monitored freezer fail. Interim storage of frozen allograft on the unit will be in a Styrofoam container with dry ice, which is obtained from the Blood Bank.

6. When using the bone freezer:
 - a. appropriate thermal gloves must be worn to protect the skin;
 - b. donor bone or tissue is placed into the freezer in the same packaging in which it was received (without any Styrofoam container)
 - c. the physician / surgeon who anticipates the need for a particular type of bone or tissue is responsible for arranging the order through Materials Management;
 - d. bone or tissue is removed from the freezer only when the surgeon is sure of the need for it; and
 - e. bone / tissue may not be returned to the freezer if it has been contaminated or has begun to thaw.
7. Tissue will be delivered to the sterile field in an aseptic manner. Routine culturing of tissue on the sterile field prior to use of the implant or device is not advised. Clinical staff will adhere to package insert information regarding:
 - a. instructions for use
 - b. indications and contraindications
 - c. preparation of tissue for use
 - d. expiration dates
 - e. specific tests performed on the tissue
 - f. warnings and potential adverse reactions
 - g. instructions for opening packages or containers
8. Disposition of the tissue will be logged to include:
 - a. date of use / disposition
 - b. receiving patient name and MRN
 - c. surgeon / dentist of record
 - d. name of procedure performed

The tissue identification number will be documented in the medical record, including a description of the tissue device or tissue implant, along with any other unique identifying information. Clinical staff will supply recipient information to the tissue supplier to comply with federal regulations and complete any information that the patient is to receive. Records will be kept for a period of no less than 10 years.

Tissues transferred to another facility or back to the source facility must also be recorded as such.

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9. Tissue with packaging that is intact and unopened and that has been stored in an appropriate environment may be returned within 24 hours of the scheduled surgery date, pending agreement by the supplier. Exceptions to this may be made only by the nurse manager or their designee' in conjunction with the attending surgeon.
10. Adequate records will be maintained by Materials Management staff for tracking of receipt and storage of all tissue devices and tissue implants. All packing slips, etc., will be kept on file until the tissue is used in a procedure.
11. Materials Management personnel will inventory the freezer contents twice weekly and post notice of items on-hand on the freezer door. Materials Management personnel will defrost the freezer per schedule or as needed, whichever occurs first.
12. Temperature monitoring will be ongoing through the hardwired connection with the Environmental Control Center (ECC). Materials Management personnel will test the freezer quarterly for temperature alarm function.
13. Adverse reactions to tissue devices or implants, including infection, will be reported to the implanting physician / dentist, Risk Management, Infection Control and in accordance with the Safe Medical Devices Act. Adverse reactions to non-device tissue implants, such as transmission of disease via tissue graft, unanticipated graft failure, or other fatal or adverse reactions arising from the receipt of tissues will be done according to current FDA regulations. The *psn* system will be used to document all adverse reactions.
14. Any tissue reported by a source facility as the cause of possible infection or any tissue involved in an event that may have contaminated the product will be sequestered. This will be reported to the implanting physician / dentist, Risk Management, and Infection Control, and patients who have been recipients of the tissue will be identified. John Dempsey Hospital will cooperate with all efforts to locate and inform patients of their risk.
15. Tissues that have been processed in such a manner that their functional, structural and biological characteristics have been altered are considered as biologics and are not classified as tissues. Such biologics are not governed under these guidelines. Examples of biologics include myoblasts and tissues used as part of gene therapy technology.
16. Implant tissue that has reached its expiration date or is otherwise determined to be unfit for use will be disposed of as biohazardous waste and will be so documented.
17. The religious beliefs of the patient will be supported regarding use of tissue devices and implants.

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PROCEDURE: Tissue Recall Notification

<u>Action</u>	<u>Points of Emphasis</u>
1. In the event that a supplier recalls tissue devices or implants, Materials Management staff will review the tissue inventory list to ascertain if any of the recalled tissue has been received by the hospital.	1. Update inventory list as needed.
2. Materials Management staff will notify nursing regarding any recalled tissue devices or implants, who will determine if any recalled tissue has been placed in a patient	
3. The nurse manager or designee' will notify the physician / dentist who used the recalled tissue with the following information: a. patient name(s) b. tissue device or implant used c. reason for recall of tissue	3. Notification of the patient in regard to the recall any further action to be taken is a surgeon responsibility.
4. The nurse manager or designee' will notify Risk Management with the same information as supplied to the surgeon.	4. Risk Management may collaborate as necessary with the physician / dentist.
5. Any unused recalled tissue device or implant will be handled according to supplier recommendations.	5. Materials Management staff will note in the tissue inventory book how any unused recalled tissue has been handled.

PROCEDURE: JDH OR Bone Freezer Maintenance and Operation

<u>Action</u>	<u>Points of Emphasis</u>
1. Twice weekly, check freezer contents and update the inventory list, ideally on Mondays and Thursdays.	1. Update inventory list as needed.
2. Weekly, the temperature graph will be changed: a. the insertion date and initials of the person inserting the new graph will be placed on the graph b. the removal date and initials of the person removing the graph will be placed on the graph.	2. Graphs will be kept on file for a period of 10 years. Graphs filed prior to the freezer's placement in the OR are available in the Blood bank.

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3. Monthly, inspect freezer shelves and gasket for ice and ice crystal buildup:
 - a. use dry towels to remove any loose ice crystals from shelves
 - b. gently remove any ice accumulation from the rubber gaskets.
4. Quarterly,
 - a. perform alarm activation check and document on the "Quarterly Functional Activation Check Log" posted on the side of the freezer.
 - b. vacuum the condenser and grill located at the left front of the freezer.
 - c. rinse the air filter in clean water to remove build-up, and shake to remove excess water before replacing.
5. If alarm activation falls outside of expected temperature range:
 - a. transfer contents of freezer to Blood Bank for storage, and
 - b. notify Clinical Engineering to investigate nature of problem.
3. Assures proper temperature maintenance.
4. a. press high and low alarm buttons to activate sensors; expect call from ECC within 3 minutes of activation and document this on log; notify ECC at x2348 if no call is received within 3 minutes.
 - b. arrange for vacuuming through Housekeeping.
 - c. obtain replacement filter as needed from Blood Bank.
5. a. dispose of freezer contents only upon advice of both Clinical Engineering and Blood Bank staff.

APPROVAL: Nursing Standards Committee
Tissue Management Sub-committee

Mike H. Summerer, M.D.
Hospital Director

Richard H. Simon, M.D.
Chief of Staff

EFFECTIVE DATE: 3/95

REVISION DATES: 9/97, 11/03, 4/04, 5/04, 4/06, 2/08, 5/09