Name of Policy:	**Tissue Management**
Policy Number:	3364-124-66
Department:	Nursing Service/Operating Room
Approving Officer:	Director Surgical Services
Responsible Agent:	Chief Nursing Officer
Scope:	Operating Room (OR)/Perioperative Services

THE UNIVERSITY OF TOLEDO MEDICAL CENTER

Effective Date: 12/1/2022

Initial Effective Date: July 11, 2007

_____ New policy proposal	__X__ Minor/technical revision of existing policy
_____ Major revision of existing policy	_____ Reaffirmation of existing policy

(A) Policy Statement

The Operating Room (OR) ensures that donor tissue intended for transplantation or implantation use in procedures is appropriately acquired, received, stored, issued, and documented in a controlled, systematic process to ensure the highest level of safety to each recipient.

(B) Purpose of Policy

To establish a process for the ordering, receiving, storing, and issuing and documentation of tissue in the OR.

(C) Procedure

1. Oversight

    a. The OR Operations Supervisor is the designated individual responsible for oversight of tissue management but may delegate responsibility for departmental compliance to RN service coordinators or staff members.

2. Source Facilities

    a. Tissue banks issuing allografts to UTMC must be registered as a tissue bank with the Food & Drug Administration (FDA).
    b. Tissues received from tissue banks and other source facilities must have met the required criteria set forth from the FDA.
    c. Verification of source facilities will be maintained by the Purchasing Department.

3. Tissue Transportation

    a. Containers for transportation must protect tissue from contamination and maintain tissue at the appropriate temperature range required by the manufacturer's instructions for use (IFU) during transport. Tissue should be placed in the appropriate storage location as soon as possible after UTMC receives the tissue.
    b. Tissue must be stored in a secure area with access restricted to authorized personnel.
        - Source Facility Required Tissue Labeling ID number.
        - Description.
        - Name, address and telephone number of source facility responsible for determining donor suitability, processing, storage, and distribution of the tissue;
        - Expiration date;
        - Recommended storage conditions;
        - Disinfection or sterilization method used;
        - Quantity of tissue (volume, weight, dimensions);

- Potential residues of processing agents and solutions

4. Tissue package inserts should include IFUs, indications and contraindications, preparation of tissue for use, expiration dates and specific tests preformed on the tissues, warning and potential adverse reactions, and instructions for opening containers.

5. Coordinating, Handling, and Storage of Incoming Tissue

   a. Cryopreserved tissue
      - Cardiac/Vascular service coordinator or designee will coordinate incoming tissue.
      - The service Coordinator, in collaboration with source facility vendor and in-house purchasing personnel, will set up ordering of tissue and track arrival time to facility.
      - Upon Tissue arrival, the Sub-Sterile Core (SSC) inventory control Supervisor or designee will be notified to complete the incoming tissue log.
      - The service coordinator or designee will: unpack tissue and ensure integrity of tissue packaging; check that all documentation is in order; and check that the appropriate temperature range was maintained during transport. The service coordinator or designee will secure tissue immediately to the appropriate storage location.

   b. Bone/Tissue
      - The UTMC purchasing department will coordinate the ordering of bone/tissue.
      - Receipt of bone/tissue will be coordinated by the SSC Inventory Control Supervisor or designee.
      - The SSC Inventory Control Supervisor or designee will log in bone/tissue, check package integrity, and place tissue in appropriate storage location such as the designated shelf in SSC or ultra-low temperature (ULT) freezer (i.e., bone freezer).

6. Tracking and Record Keeping

   a. The tissue inventory log will be maintained in the following UTMC OR department network folder; Z:\Purchasing\Tissue Log so that it is accessible to RN service coordinators, the SSC Inventory Control Supervisor or designee and the OR operations supervisor(s) and designees. The following information will be logged into the tissue inventory log.
      - Source facility name
      - Tissue ID/Reference number
      - Tissue lot number
      - Tissue description
      - Tissue expiration date
      - Date Implanted or Wasted
      - Patient Medical Record Number (MRN)

   b. Copy of original paperwork for veins and valves is maintained in the cardiac/vascular service coordinator's office. Original paperwork for cryopreserved tissue will be kept in the filing cabinet at the OR front desk.

   c. The RN circulator will document the complete tissue information listed in 6a also including site and laterality of implant in electronic medical record (EMR) at the time of surgery or on the paper OR record if the EMR software is offline.

   d. Similarly, the RN circulator will document the complete information of any materials used to prepare or process tissues in the EMR or on the paper OR record at the time of surgery, including:
      - Source facility name
      - Tissue ID/Reference number

- Tissue lot number
- Tissue description
- Tissue expiration date
- Implanted or wasted.

e. The circulating RN will include a tissue vendor-supplied package sticker on the resource map or will write the information from the tissue packaging on the resource map, which will include all required information (see 6a).

f. The circulating RN will complete the source facility's information card or paperwork and place it in the bone bank mailbox.

g. The final verification of implanted tissue is the responsibility of the surgical billing department. Surgical billing staff will validate the correct information and assure the correct information resides in the EMR.

7. Storage Guidelines

a. Dehydrated musculoskeletal tissue should be stored at ambient temperature or cooler. Frozen musculoskeletal and osteoarticular tissue should be stored at –40° F (–40° C) or colder for long term storage. Cryopreserved cardiovascular tissue should be stored at –148° F or –100° C or colder. Tissue in refrigerator is stored at 33.8° F (1° C) to 50° F (10° C).

b. Autologus tissue should be segregated from allografts.

c. Tissue expiration should not exceed the following recommendations of the American Association of Tissue Banks (AATB).

- Refrigerated musculoskeletal tissue: 5 Days
- Refrigerated skin: 14 Days
- Frozen and cryopreserved cells and tissue: 5 years
- Lyophilized or dehydrated tissue: 5 Years.

d. ULT freezer, liquid nitrogen freezer and refrigerator temperatures will be checked and recorded daily on a temperature log by a perioperative technician or designee.

e. The ULT freezer and liquid nitrogen freezer are equipped with an alarm system that is continuously monitored and sounds when the temperature is not within acceptable range.

f. In the event of emergency power loss, OR staff will manually check liquid nitrogen using measuring stick every hour. If level nears 4 inches, perform a manual fill. The liquid nitrogen freezer will have emergency backup power.

g. Tissue stored at ambient temperature will have the temperature checked and recorded daily on a temperature log kept by the SSC Inventory Control Supervisor or designee or perioperative technician in the OR.

8. For adverse events – See Infection Control Policy 3364-109-DIS-209. "Healthcare personnel who become aware of adverse events or infections of recipients of tissue or organ transplant will notify Infection Prevention, who will notify the Risk Manager and the Surgical Administrator".

9. Tissue Recall

a. In the event that the FDA or issuing facility initiatives a product recall, the OR will determine if the recall is applicable to the department.

b. If any patient has received the recalled tissue, Risk Management will be notified for investigation and follow up.

c. If any product is in the institution, it will be removed from storage immediately.

Approved by: /s/ Michelle Mallette, MSN, RN, CNOR Director Surgical Services — Date /s/ Kurt Kless, MSN, MBA, RN, NE-BC Chief Nursing Officer — Date Review: Policy & Standard Committee, 10/2011, 2/16, 8/19, 12/22 Revision completed by: Ronni Zona, RN, BSN, CNOR Perioperative Nurse Educator	**Review/Revision Date:** 11/10/2008 12/3/2008 10/28/11 2.1.2016 8/1/2019 12/1/2022 **Next Review Date:** 12/2025
Policies Superseded by This Policy: 4-66	

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.