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Origination 4/19/2023 Document Wendy Frizzo: Contact **Bone and Tissue** 3/14/2024 Last Coordinator Approved Area Laboratory-Blood Effective 3/4/2024 Bank Last Revised 3/14/2024

Applicability

FH, GP, RO, Troy

Next Review 3/14/2026

Issue of Tissue Products

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide Transfusion Medicine staff members with specific guidelines for inspecting tissues upon issuance to the operating room (OR) and for documentation of the issuance process. Compliance to these guidelines will promote the quality and traceability of each tissue provided by the Transfusion Medicine.

II. CLINICAL SIGNIFICANCE:

Inspecting a tissue prior to issue is an important step in the issuing process. The integrity of a tissue product may be compromised inadvertently during storage and repetitive issuance. Frequent movement in and out of freezers may damage packaging, accidental breakage may occur, tissue may fracture, and seal integrity may become compromised. Before the tissue is dispensed from Transfusion Medicine, the outgoing tissue must be inspected, issued in the computer system and proper documentation of issue to the operating room must be recorded. In addition, instructions need to be provided to the transporter at the time of issue on proper handling of the product during transport.

III. SPECIAL SAFETY PRECAUTIONS:

Tissues are bio-hazardous materials. Any broken or compromised tissues should be handled using standard precautions.

IV. PROCEDURE:

A. Inspecting and Issuing Tissue:

Action	Notes
1. Examine the tissue request form for patient name and hospital medical record number and select tissue(s) from the inventory as indicated on the request form.	A. Tissue requests must be documented on a Tissue Request Form. The patient's identification number and complete name must be in the upper right-hand corner of the form.
	B. A band number is not required to issue tissue. Multiple tissues may be issued to a single patient.
 2. Inspect each selected tissue for: A. Legible, affixed tissue ID label B. In-date expiration date C. Package insert D. Package integrity 	 A. Label description of tissue matches the tissue within the package. If the packaging is sealed, assume it matches. B. Inspection of package integrity should include: 1. Frozen tissue: a. No evidence of the graft penetrating the packaging b. No evidence cracks or fractures in packaging
	2. Refrigerated tissue:
	a. No evidence of the graft penetrating the packaging
	b. Protective seal is intact (corneas and sclera)
	c. No evidence of cracks or fractures in packaging

3. Lyophilized tissue: a. No evidence of cracks or fractures in packaging b. Protective seal is intact 4. Apligraft: a. No evidence cracks or fractures in packaging b. Protective seal is intact c. Check the pH of agarose gel using the affixed colorcoded pH chart C. Quarantine any tissue found to be deficient. Document discrepancies using the on-line Internal Variance form. Refer to site specific Transfusion Medicine policy for variance reporting and notify the Hospital Tissue Coordinator or Blood Bank Supervisor. 4. Issue the tissue in the TrackCore application. Refer to Transfusion Medicine policy, TrackCore (Tissue) Application; Issuing Tissue. 5. Place one TrackCore patient and tissue label Retain this copy in the department. on the Tissue Request form with out covering any original documentation. 6. Place remaining TrackCore patient and tissue labels in the corresponding boxes in Section 1 on F-3520 (for both white and yellow copies). 7. Document by placing a $\sqrt{\text{next to the Special}}$ A. Special Instructions: Instructions in Section 1 on F-3520, Special The graft should remain on: Instructions. 1. Room Temperature 2. Wet ice

	3. Dry ice4. Liquid N₂
8. Document the following in Section 2 of F-3520 under the <i>Tissue Issue</i> column: A. Issue to	A. Issue to : Employee ID number, OR aide name, or name of person picking up the tissue.
B. Issuing technologistC. Issue date and time	 B. Issuing technologist: initials or employee ID number of the technologist dispensing the tissue.
	C. Issue date and time: Electronic time stamp or handwritten documentation of the date & time of when the tissue is dispensed.
9. Attach the corresponding form F-3520 to the tissue (both white & yellow copies).	A. Tape may be used to attach the form to tissues stored at room temperature.B. Placing the graft in a biohazard bag and placing F-3520 in the outer pocket is also acceptable.
10. Place the tissue in the appropriate temporary transport device.	 A. Frozen tissue: Styrofoam™ Frozen Tissue Cooler B. Refrigerated tissue: Igloo® Human Tissue Cooler, A, B, C, etc C. Liquid Nitrogen: Liquid Nitrogen Dewar D. Tissue stored at room temperature may leave Transfusion Medicine in biohazard transport bags.

B. Instruction to Transporters at the Time the Tissue Product is Dispensed:

Action	Notes
1. Affix written instructions stating the handling tissue while in the transporters custody.	A. The technologist will affix written instructions or confirm written instructions for transport are on tissue product transport containers to promote proper transport and prompt delivery to the OR.

V. SPECIAL NOTES:

Tissue brought in by sales representatives will only be accepted if the sales representative is registered with the Food and Drug Admistration (FDA) as a distributor. Tissue should be received directly from the supplier or manufacturer.

VI. REFERENCES:

- A. AABB, Standards for Blood Banks and Transfusion Services, current edition
- B. American Association of Tissue Banks, Standards, current edition

Approval Signatures

Step Description	Approver	Date
	Masood Siddiqui: Staff Pathologist	3/14/2024
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Applicability

Farmington Hills, Grosse Pointe, Royal Oak, Troy

