

Beaumont

Origination 4/19/2023
 Last Approved 3/20/2023
 Effective 4/19/2023
 Last Revised 3/20/2023
 Next Review 3/19/2025

Document Contact Wendy Frizzo:
 Bone and Tissue Coordinator
 Area Laboratory-Blood Bank
 Applicability Farmington Hills, Royal Oak, Troy

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.	<p>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.</p> <p>B. A band number is not required to issue tissue. Multiple tissues may be issued to a single patient.</p>
2. Inspect each selected tissue for: <p>A. Legible, affixed tissue ID label</p> <p>B. In-date expiration date</p> <p>C. Package insert</p> <p>D. Package integrity</p>	<p>A. Label description of tissue matches the tissue within the package. If the packaging is sealed, assume it matches.</p> <p>B. Inspection of package integrity should include:</p> <p>1. Frozen tissue:</p> <p>a. No evidence of the graft penetrating the packaging</p> <p>b. No evidence cracks or fractures in packaging</p> <p>2. Refrigerated tissue:</p> <p>a. No evidence of the graft penetrating the packaging</p> <p>b. Protective seal is intact (corneas and sclera)</p> <p>c. No evidence of cracks or fractures in packaging</p>

	<p>3. Lyophilized tissue:</p> <ul style="list-style-type: none"> a. No evidence of cracks or fractures in packaging b. Protective seal is intact <p>4. Apligraf:</p> <ul style="list-style-type: none"> a. No evidence cracks or fractures in packaging b. Protective seal is intact c. Check the pH of agarose gel using the affixed color-coded pH chart <p>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.</p>
3. Perform an electronic crossmatch in the Transfusion Medicine computer system using the correct current tissue CDMs and print the corresponding Tissue Graft Information Form (F-3520) for each tissue.	Refer to Tissue CDMs: Selecting Tissue for Issue or Alternative Method: Selecting and Issuing Tissue Product(s)
4. Perform the issuance process in the Transfusion Medicine computer system.	Refer to CDM: Issuing Tissue
5. Document by placing a ✓ next to the Special Instructions in Section 1 on F-3520, <i>Special Instructions</i> .	<p>A. Special Instructions: The graft should remain on:</p> <ul style="list-style-type: none"> 1. Wet ice 2. Dry ice 3. Liquid N₂
6. Document the following in Section 2 of F-3520 under the <i>Tissue Issue</i> column:	A. Issue to: Employee ID number, OR aide

<p>A. Issue to</p> <p>B. Issuing technologist</p> <p>C. Issue date and time</p>	<p>name, or name of person picking up the tissue.</p> <p>B. Issuing technologist: initials or employee ID number of the technologist dispensing the tissue.</p> <p>C. Issue date and time: Electronic time stamp or handwritten documentation of the date & time of when the tissue is dispensed.</p>
7. Remove the white copy of the F-3520 and staple to the request form.	
8. Attach the corresponding form F-3520 to the tissue (yellow & pink copies).	<p>A. Tape may be used to attach the form to tissues stored at room temperature.</p> <p>B. Placing the graft in a biohazard bag and placing F-3520 in the outer pocket is also acceptable.</p>
9. Place the tissue in the appropriate temporary transport device.	<p>A. Frozen tissue: Styrofoam™ Frozen Tissue Cooler</p> <p>B. Refrigerated tissue: Igloo® Human Tissue Cooler, A, B, C, etc...</p> <p>C. Liquid Nitrogen: Liquid Nitrogen Dewar</p> <p>D. Tissue stored at room temperature may leave Transfusion Medicine in biohazard transport bags.</p>

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 Administration (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
Policy and Forms Steering Committee (if needed)	Kristina Davis: Staff Physician	3/20/2023
	Ryan Johnson: OUWB Clinical Faculty	1/18/2023
	Vaishali Pansare: Chief, Pathology	1/17/2023
	John Pui: Chief, Pathology	1/11/2023
	Wendy Frizzo: Bone and Tissue Coordinator	1/11/2023
	Gail Juleff: Project Mgr Policy	11/8/2022
	Teresa Lovins: Supv, Laboratory	11/8/2022
	Karrie Torgerson: Supv, Laboratory	11/7/2022
	Rebecca Thompson: Medical Technologist Lead	11/3/2022
	Wendy Frizzo: Bone and Tissue Coordinator	10/27/2022
Policy and Forms Steering Committee (if needed)	Wendy Frizzo: Bone and Tissue Coordinator	10/27/2022