



Policy: Implantable Tissue: Receipt, Storage, Use and Documentation

Effective: 02/06/24

Identifier: S-FW-TS-0002

Acute Care: ENC GR LJ MER Ambulatory SHAS

PURPOSE: To outline the requirements for implantable tissue and the traceable documentation method necessary for investigation of adverse events and recalls.

I. POLICY

- A. All vendors providing, storing, and transporting of Human cellular and tissue-based products (HCT/P's) as defined by the FDA must be registered as a Tissue Establishment by the FDA, accredited by the American Association of Tissue Banks (AATB), and licensed as a Tissue Bank by the State of California. Refer to **Attachment:** Tissue Supplier Requirements.
- B. Tissue is received by Supply Chain Management or Surgical Services Designee.
- C. All tissue will be stored at the instructed manufacturer's temperature requirements in a secured area designated for this purpose.
- D. All documentation of use and disposition of tissue is recorded in the electronic medical record (eMR) or **Related Form C:** Tissue Tracking Log.

II. DEFINITIONS

- A. HCT/P: Human cellular and tissue-based products containing or consisting of human cells or tissues and intended for implantation, transplantation, infusion, or transfer into human recipients, including investigational products as defined by the U.S. Food and Drug Administration (FDA).
- B. Tissue: Human and non-human cellular based transplantable and implantable products whether classified by the U.S. Food and Drug Administration (FDA) as a tissue or a medical device. If the end product contains cellular elements, the standards apply. **NOTE:** If the end product is acellular then the standards do not apply even though it may have been originally extracted from human or animal cellular products. Collagen and tissue products derived from plastics and polymers are not considered cellular-based products and are not evaluated under these standards.

III. PERSONNEL

- A. Surgical Services Registered Nurses (RNs)
- B. Supply Chain Management
- C. Surgical Coordinators
- D. Operations Supervisor
- E. Surgical Services Leadership
- F. Vendors

IV. PROCEDURES

- A. Receipt of Tissue
 1. Tissues are received by designated personnel (e.g., Supply Chain Management or Surgical Services Designee).
 2. Verify package integrity and the expiration date of the product at the time of receipt. Any defective or damaged packaging or product will be rejected.
 3. Verify that the temperature range was controlled during transport and acceptable for tissue requiring a controlled environment.

4. Document in the "receipt" section in the eMR or Tissue Tracking Log:
 - a. Date and time the Tissue is received
 - b. Package integrity is acceptable
 - c. Transport temperature range has been maintained, if applicable
 - d. Tissue type and description of tissue
 - e. Tissue ID, Serial number, Lot number
 - f. Manufacturer
 - g. Site location
 - h. Signature of the person receiving the tissue
 5. The Tissue Tracking Log and delivery ticket will be attached to the tissue package.
- B. Storage of Tissue

Tissue is stored according to manufacturer's instructions.

1. Refrigerators and freezers used to store tissue will be maintained at a controlled temperature, continuously monitored, and have functional alarms.
2. Temperatures of tissue refrigerators will be checked and recorded daily. Exception: Tissue requiring no greater control than ambient temperature (defined as the temperature of the immediate environment) for storage do not require temperature monitoring.
3. In the event of refrigeration failure or power outage, notify Surgical Services leadership immediately. After hours, the Operations Supervisor will be notified to contact the tissue vendor representative. The tissue vendor representative will transport the tissue to their facility to maintain the HCT/P at the correct storage temperature.

C. Use of Tissue

1. Before use, package integrity is verified by the circulating RN. Any tissue or packaging found to be damaged will not be used.
2. Tissue is used according to manufacturer's instructions for handling, reconstitution (as indicated), and implantation.
3. A copy of the manufacturer's instructions for use may be accessed using OneSource.
4. Document the following in the implant section of the eMR or Tissue Tracking Log:
 - a. Any materials/solutions used to prepare or process the tissue for use.
 - b. Tissue use:
 - i. Detailed description of the type of tissue
 - ii. Unique tissue identification or lot number
 - iii. Size (if applicable)
 - iv. Company and catalog number (when applicable)
 - v. Expiration date (when applicable)
 - vi. Quantity and site of implantation
 - c. The Circulating RN will document the following:
 - i. Date tissue is used.
 - ii. Time tissue is removed from freezer or refrigerator (*not applicable for tissue stored at ambient temperature*)
 - iii. Time tissue is implanted.
 - iv. Verification that package integrity
 - v. Name of staff issued the tissue.

- vi. Name of staff who prepared the tissue.
 - vii. Verification that tissue was prepared in accordance with manufacturer's guidelines and instructions for use.
 - viii. Amount and type of reconstitution fluid, start and end time of reconstitution, and lot number of reconstitution fluid as applicable in accordance with manufacturer's guidelines and instructions for use.
 - ix. Name of surgeon
 - x. Final disposition of tissue (Refer to Section D below)
5. Circulating RN will complete any Tissue Usage cards or records for return to the supplier.
- D. Disposition of Tissue will have the following outcomes:
1. Tissue was implanted.
 2. Tissue was received but not implanted. Document as:
 - a. Wasted
 - b. Returned to vendor.
 3. The person disposing the tissue will document final disposition.
- E. Record Keeping
1. In the event of downtime procedures, pertinent paper forms and records will be scanned into the eMR. If used during a downtime event, the Tissue Tracking Log (**Related Form C**) is filed with the end of case paperwork. The Surgical Supply Chain Coordinator files the completed log in the Tissue Tracking Log File by year and manufacturer or as per protocol.
 2. All paper records relating to tissue implantation will be maintained according to regulatory requirements; refer to *Record Retention and Destruction Schedule; SW-IM-0600 A* (policy *Record Retention, Storage, Retrieval, and Destruction; S-FW-IM-0600*).

V. REFERENCES

- A. California Health and Safety Code
- B. AATB Standards for Tissue Banking, current edition.
- C. Department of Health and Human Services, Food and Drug Administration
- D. The Joint Commission Hospital Accreditation Standards current edition

VI. RELATED PRACTICE DOCUMENTS

- A. Record Retention, Storage, Retrieval, and Destruction; [S-FW-IM-0600](#) and Record Retention and Destruction Schedule; [SW-IM-0600 A](#)
- B. Recalls, Product Hazards and Alerts; [S-FW-EC-6002](#)
- C. Required Reporting to Regulating and Outside Agencies; Leadership Responsibilities; [S-FW-LD-2002](#)

VII. RELATED FORMS

- A. Implant Record, Downtime; [100-7420-772SW](#)
- B. Intraoperative Documentation, Downtime; [100-NS7420-180SW](#)
- C. Tissue Tracking Log; [100-NS8720-648SW](#)

VIII. ATTACHMENT

Tissue Supplier Requirements

IX. SUPERSEDED

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Document Chronology		
Original: 09/14	Revised: 02/18, 12/20, 01/24	Reviewed:
Development Summary		
01/24 Revised:		
<ul style="list-style-type: none"> - A copy of the manufacturer's instructions for use may be accessed using OneSource. It no longer needs to be included in the medical record. - Documentation includes amount and type of reconstitution fluid, start and end time of reconstitution, and lot number of reconstitution fluid as applicable in accordance with manufacturer's guidelines and instructions for use 		
Development Workgroup		
Representation	Member Name	Member Title/Discipline
Owner/ Workgroup Leader	Jose Ferreira	Director, Surgical Services/GR
SHAS Representative	Joanna Gerlt	Director, Regulatory Readiness
Clinical Mentor	Anthea Eichmann	Clinical Mentor/MER
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LJ Representative	Elena Giardino	Director, Surgical Services
MER Representatives	Linda Ferrick Diane Schloeder	Director, Surgical Services Director, Regulatory Readiness
CFLI Representative	Carmina Esteban	Professional Development Specialist
EMR Representative	Aubrey Thompson	Manager, Information Management
Supply Chain Representative	Stacy Griffin	Director, Supply Chain
SMF/ASC Representative	Amy Wilke	Regulatory/Accreditation Coordinator
Endorsements & Approvals		
Function	Chair Name/Title/Position	Date
Executive Sponsor	Cecile Hozouri, CVP/Supply Chain Mgmt	01/16/24
ID Council	Gonzalo Ballon-Landa MD	01/15/24
Surgery Care Line	Cecile Hozouri, CVP/Supply Chain Mgmt	01/10/24
Corporate Quality (Interim Corporate Surgical Services)	Craig Uejo, CVP, Chief Quality Officer	01/16/24
Executive Cabinet	Chris Van Gorder, President & CEO	01/23/24

ATTACHMENT: Tissue Supplier Requirements

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All tissue suppliers, or third party, that provides, stores, distributes, or transports HCT/Ps (as defined by the FDA) must provide proper documentation evidencing the following prior to entering a business relationship with Scripps Health.

1. A photocopy of registration as a certified Tissue Establishment by the FDA, accredited by AATB, and licensed as a Tissue Bank by the State of California.
2. A signed statement of intent to comply with the FDA's *Good Tissue Practices* and *Donor Suitability* regulations and the AATB's *Guidance Document: Prevention of Contamination and Cross-Contamination at Recovery: Practices and Culture* when providing and storing HCT/Ps.
3. Qualified shipping containers, with expiration dates (as defined by FDA), are used when transporting HCT/Ps.
 - a. The transport pathway is under the auspices of an approved tissue supplier and that the containers are properly qualified.
 - b. This includes documentation for any third-party suppliers that provide HCT/P products to any of Scripps' facilities on the primary supplier's behalf. If any third-party supplier does not have a California Tissue Bank license such third party supplier is prohibited by California law from bringing any HCT/P product into the state and any of Scripps Health's facilities.
4. The transport temperature must be verified pursuant to the tissue type being transported. Proper temperature for the tissue was maintained throughout the transport pathway.
5. All HCT/Ps when they are received into the hospital must be accompanied with a package insert which specifies the accreditation / regulatory prescribed information including, but not limited to:
 - Tissue description
 - Documentation statement of testing and screening
 - Storage requirements
 - Preparations for use
6. A centralized logging record will be maintained at each site for the receipt and final disposition of all HCT/Ps (implanted, returned, and discarded). Documentation elements include the following:

Receipt
Date
Time
Received By
Source Supplier
Storage Supplier
Tissue Type
Tissue Identification / Serial Number
Expiration Date
Container Inspection ¹
Transport Temperature Verification ²
Package Insert Present ³

¹Usable, Compromised

²Verified, Not Verified

³Present, Missing

7. All tissue usage information cards must be completed and returned to the tissue source / storage supplier when requested.
8. If the tissue container is damaged to where it adversely affects the tissue and/or the receiving temperature is not within transport parameters, the tissue will be rejected.