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

IDENTIFIER: S-FW-TS-0002	**EFFECTIVE DATE: 3/6/18**				
	☒ **Acute Care:**	**ENC**	**3/6/18**	**GH**	**3/6/18**
APPROVED: Executive Cabinet 2/20/18		**LJ**	**3/6/18**	**MER**	**3/6/18**
ORIGINAL: 09/14	☐ **Ambulatory:**	**SMF**			
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KEYWORDS: Surgical Services, Implantable Tissue, Human Tissue, Donor, Recipient

I. PURPOSE

To outline the requirements for receipt, storage and use of implantable tissue. Outline the method of traceable documentation in order to investigate adverse events, including, but not limited to, recalls and donor/recipient infections.

II. POLICY

A. All vendors providing, storing, and transporting 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.

B. Tissue is received by Supply Chain Management, Surgical Services, or Laboratory Designee as per facility process.

C. All tissue will be stored at the instructed manufacturer's temperature requirements in a secured room designated for this purpose.

D. Record keeping of the use and disposition of tissue is recorded in the electronic medical record and / or the Tissue Tracking Log and Implant Record by the Circulating RN. In the event that the electronic medical record documentation is not accessible, paper documentation and downtime procedures will be observed.

III. 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. Collagen and tissue products derived from plastics and polymers are not considered cellular-based products and are not evaluated under these

standards. 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.

IV. PERSONNEL

A. OR RNs
B. Supply Chain Management / Surgical Coordinators
C. Operations Supervisor
D. Laboratory Clinicians
E. OR Management
F. Vendors

V. PROCEDURES

A. Receipt of Tissue
   1. Tissues are received by designated personnel; Supply Chain Management, Surgical Services, or Laboratory Designee as per facility practice.
   2. Package integrity and the expiration date of the product will be verified 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. Designated personnel will record the following information in the electronic medical record / Tissue Tracking Log in the receipt section of the documentation:
      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. (Not applicable for locations that have gone live with Epic)

B. Storage of Tissue
   1. Tissue is stored according to manufacturer's instructions.
      a. Refrigerators and freezers used to store Tissue will be at a controlled temperature, continuously monitored, and have functional alarms. Daily temperature logs will document that tissues are stored in a controlled environment are stored at required temperatures. Note: Tissue requiring

no greater control than ambient temperature, defined as the temperature of the immediate environment, for storage do not require temperature monitoring.

b. Should the temperature monitor alarm in the event of refrigeration or freezer failure, or power outage the Surgical Services Management will be notified. In their absence the Operations Supervisor will 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 checked by the circulating RN. Any tissue or packaging found to be damaged will be rejected.
2. Tissue is used according to manufacturer's instructions for handling, reconstitution (as indicated), and implantation.
   a. A copy of the manufacturer's instructions for use must be included in the patient's permanent medical record.
3. Materials used to prepare or process the tissue for use will be recorded in the electronic medical record or on the Tissue Tracking Log.
4. Use of tissue is documented on the Patient Implant Record. This includes a detailed description of the type of tissue, unique tissue identification or lot number, size (if applicable), company and catalog number (when applicable), expiration date (when applicable), and quantity and site of implantation.
5. Tissue usage cards or records provided by the supplier are completed by the Circulating RN and returned to the supplier.
6. The Circulating RN will document on the implant section of the electronic medical record or the Tissue Tracking Log in the Implantation section the following information:
   a. Date of tissue usage.
   b. Time tissue is removed from freezer or refrigerator. Time of removal for tissue stored at ambient temperature is not applicable. Time tissue is implanted.
   c. Verification that package integrity has been maintained.
   d. Name of staff tissue is issued to.
   e. Name of staff tissue is prepared by.
   f. Verification that tissue was prepared in accordance to manufacturer's guidelines.
   g. Amount and type of reconstitution fluid if used.
   h. Surgeon's name.
   i. Tissue Recipient; Patient's name and MRN number. Use patient label.
   j. Disposition of tissue.

D. Disposition of Tissue

1. Disposition of Tissue will have the following outcomes:
   a. Tissue was implanted.
   b. Tissue was received but not implanted. Document as:

i. Wasted.
ii. Returned to vendor.

2. Person disposing the Tissue will document in the electronic medical record or sign the Tissue Tracking Log.

E. Record Keeping

1. The Tissue Tracking Log 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 for a period of ten years beyond the date of distribution or disposition of the tissue. Tissue that is implanted is documented in the patient's electronic medical record. In the event of downtime procedures, pertinent paper records will be scanned into the electronic medical record.

VI. REFERENCES

A. California Health and Safety Code 1644.5(a)

B. AATB Guidance Document Prevention of Contamination and Cross Contamination at Recovery: Practices and Culture Results, No. 2, version 2, 5-29-07

C. AATB Standards for Tissue Banking, 13th edition.

D. Department of Health and Human Services, Food and Drug Administration: Current Good Tissue Practices for Human Cell Tissue and Tissue-Based Product Establishments, Inspection and Enforcement, Final, 21 CFR Parts 16, 1270 and 1271, Federal Register.

E. Joint Commission Standards 2013, TS.03.01.01, TS.03.02.01, and TS.03.03.01 Transplant Safety.

VII. RELATED POLICIES

Recalls, Product Hazards and Alerts; S-FW-EC-6002

VIII. RELATED FORMS

Implant Record; 100-7420-772SW (reviewed 11/17)

IX. ATTACHMENTS

A. Scripps Tissue Tracking Log Form
B. Tissue Supplier Requirements

X. SUPERSEDED

Implantable Tissue: Receipt, Storage, Use, and Documentation, 09/14

DEVELOPMENT SUMMARY		
2/18 revision: Updated policy verbiage to align with EMR		
Development Workgroup		
Representation	**Member Name**	**Member Title/Discipline**
Workgroup Leader/Author	Bruce Grendell	Director OR Services, SGH
Workgroup member	Charlotte Hyre	RN, informatics
Workgroup member	Alan Boren	Inventory Management Specialist
Workgroup member	Lorin Birmingham	Clinical Resource Specialist, Supply Chain
Encinitas Representative	Jan Lee Kwai	Director OR Services
La Jolla Representative	Bernadette Robertson	Director OR Services
Mercy Representative	John Plasse	Director OR Services
CFLI Representative	Carmina Esteban	Professional Development Specialist

ENDORSEMENTS and APPROVALS		
Function	**Chair Name/Title/Position**	**Date of Endorsement and Approval**
Executive Sponsor	Lisa Thakur, Corp VP, Horizontal Operations	1/23/18
Surgical Care Line	Lisa Thakur, Corp VP, Horizontal Operations	1/23/18
Infection Control	Andrea Godinez, Dir, Regulatory Affairs and Infection Prevention	11/13/17
Executive Cabinet	Chris Van Gorder, President & CEO	2/20/18

Attachment A: Tissue Tracking Log Form

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RECEIPT									
DATE	TIME	PACKAGE INTEGRITY	TRANSPORT TEMPERATURE RANGE MAINTAINED	TISSUE TYPE	TISSUE ID/SERIAL NO./LOT NO.	EXP DATE	MFG NAME OR VENDOR	SITE LOCATION	RECEIVED BY
	_____RECEIPT _____ DELIVERED TO STORAGE	☐ USABLE ☐ COMPROMISED	☐ YES ☐ NO ☐ N/A, ROOM TEMP					☐ CV ☐ ENC ☐ GN ☐ LJ ☐ ME ☐ SCCV	

IMPLANTATION / DISPOSITION							
DATE	TIME	ISSUE/DISPOSED BY, RN SIGNATURE	TISSUE PREPARED BY	PREPARED ACCORDING TO MANUFACTURER GUIDELINES	DISPOSITION	SURGEON	TISSUE RECIPIENT LAST NAME, FIRST NAME MEDICAL RECORD NUMBER
	_____ removed from refrigerator or freezer _____ implanted			☐ YES ☐ NO RECONSTITUTION MEDIA ☐ MFG CARD COMPLETED	☐ IMPLANTED ☐ WASTED ☐ RETURNED TO VENDOR		PATIENT LABEL PREFERRED

RETURN COMPLETED FORM TO SUPPLY CHAIN MANAGEMENT

***** IT IS THE CIRCULATING NURSE RESPONSIBILITY TO COMPLETE THE IMPLANTATION/DISPOSITION SECTION FOR EACH TISSUE *****

A. RECEIPT SECTION

Record the following information:

1. Date – The date the tissue was checked into the facility
2. Time – The time the tissue was checked into the facility and the time the tissue was delivered to storage
3. Package integrity
   a. Usable – Tissue is safe to implant in patient
   b. Compromised – Tissue is not in safe condition
4. Transport Temperature Range Maintained if frozen or refrigerated
5. Tissue type 0- describe the tissue received
6. Tissue ID/Serial#/Lot# - Found on packaging containing tissue
7. Expiration Date – Found on packaging containing tissue
8. Manufacturer/Vendor – Company from which tissue was received
9. Site Location – indicate appropriate facility
   a. CV – Chula Vista
   b. ENC – Encinitas
   c. GN – Green
   d. LJ – La Jolla
   e. ME – Mercy
   f. SCCV – Carmel Valley
10. Received By – Signature of individual completing this section of the log

B. IMPLANTATION/DISPOSITION

Record the following information:

1. Date – The date the tissue was implanted
2. Time – The time the tissue was removed from freezer or refrigerator. The time the tissue was implanted
3. Issued/Disposed by – Signature of EN completing this section of the log
4. Tissue Prepared by – Usually the scrub person; may add another person if scrub had assistance
5. Prepared in accordance with manufacturer's instructions for use
   a. Please complete the "RECONSTITUTION FLUID LOT/SN NO" & "EXP DATE". This information is on the inside of the packaging.
   b. Mfg. Card Completed – RN documented appropriate information on card
6. Disposition
   a. Implanted – Tissue was used in patient
   b. Wasted – Tissue was not implanted in patient and was discarded
   c. Returned to vendor – Tissue was not implanted in patient and was returned to the manufacturer
7. Surgeon – Surgeon implanting the tissue
   Tissue Recipient – patient information.

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 to before they may enter into 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 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]

[1]Usable, Compromised
[2]Verified, Not Verified
[3]Present, 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.