# PROCEDURE

**Title:** Tissue Transplant Policy

**Procedure #:** 2015Tissue02

Institution: Highlands Regional Medical Center

Address: 3600 Highlands Avenue, Sebring Florida 33870

Prepared by: Anita Smith Date: 6/4/2015

Title: Laboratory Administrative Director

Accepted by: _____ MD Date: 6-9-15

Title: Laboratory Medical Director

Date Patient Testing Implemented: 6/8/2015

Review of procedure every two years

Reviewed by: _____ Date: _____

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Reviewed by: _____ Date: _____

Discontinued testing date: _____

Highlands Regional MEDICAL CENTER

**Policy Name: Use of Tissue for Procedures** **Department: Surgical Services**

**Departmental Review:** **Policy #: 003-SS-100**

**INITIATE DATE** **DATE REVIEWED/REVISED** **PAGE 1 of 3**
**04/23/08** **07/13/10, 11/10/2011,11/12/2013, 11/14/2014**

## POLICY

The use of tissue for procedures involves a defined tracking process that can easily be traced. The process will help ensure that the patient receives uncontaminated tissue in an aseptic fashion. This policy will be directed toward the use of non-refrigerated tissue. Further information may be obtained from the AORN Standards, the American Association of Tissue Banks (AATB), and the FDA (Food and Drug Administration).

The Director, Charge Nurse, RN Circulator, of the Operating Room or the Clinical Manager of the facility are directly responsible for the tissue process.

## PROCEDURE

1. Tissue ordering, receiving, and storage should be handled through the Health Care Facility.

2. Before the tissue is ordered, documentation will be obtained from the facility, that they are an approved tissue bank facility by the FDA (Food and Drug Administration). You may also obtain this information from their website: *"http:/www.fda.gov"*. Proof of licensure with the State of Florida must also be obtained. These must be requested annually and kept on file.

3. The tissue or storage package should be labeled with the following information:

   - name, address, and telephone number of the tissue bank responsible for the processing, storing and distributing the tissue.

   - Allografts should have information regarding the donor the tissue was acquired from, date the tissue was procured and expiry date, the test results of the screening process and the reconstitution instructions.

   - Irradiated bone should have the tissue number, expiration date, information regarding the screening process and reconstitution instructions.

4. The incoming tissue should be recorded in a log using:

   - the name of the tissue, lot number, and expiration date

- source facility
- identification of the person accepting the tissue
- the date and time of the receipt of the tissue
- verification of the packaging integrity
- temperature was maintained during transport

5. The tissue will be stored in an environment consistent with the manufacturer's written instructions. The temperature of the environment will be monitored in a log, on a daily basis. Any deviations from the manufacturing directions should be reported to the source facility, to determine if tissue is safe for usage.

6. The tissue will be stored in a secure location with access restricted to authorized personnel.

7. Upon releasing the tissue for use, the tissue must be signed out by the authorized designee including the name of the patient, DOB (date of birth), medical record number, date issued, and Physician name. The sign out sheet will be given to the circulator or clinician in the case to document the reconstitution of the tissue (name of fluid, conc. of fluid, lot# and amt. used). Any tissue not used should be documented and discarded as biohazard waste and also be entered on the inter-operative record. Sheet to be returned to log at the completion of case.

8. The insertion or application of tissue during a procedure must be documented on informed consent.

9. Before the introduction of the tissue to the sterile field, the contents of the package should be verified by the physician. The contents of the package, expiration date and any other pertinent information should be read and verified before the tissue is dispensed onto the sterile field.

10. All tissue records must be kept for a period of 10 years after the tissue is dispensed.

11. Any adverse reactions of the patient to the tissue insertion should be immediately reported to the physician, documented on an event report and risk manager notified.

Resources:

"AORN Standard, Recommendations and Guidelines," 2011 Edition pp, 201-213

Joint Commission Website,"*http:/www.fda.gov*".