VALLEYCARE
OLIVE VIEW-UCLA MEDICAL CENTER/HEALTH CENTERS
POLICY & PROCEDURE

NUMBER: 326
VERSION: 4

SUBJECT/TITLE: **PROCUREMENT AND MANAGEMENT OF TISSUE**

POLICY: In order to ensure proper management, the procurement of tissue for the purpose of implantation or transplantation shall be obtained and tracked using the established procurement process.

PURPOSE: To define a policy and procedure for the procurement, handling, tracking, storage, use, and return of tissue used for implantation or transplantation.

DEPARTMENTS: All

DEFINITIONS: **Tissue**, for purposes of this policy, is defined as any human or non-human cellular-based implantable and transplantable products and includes, but is not limited to bone, cornea, skin, heart valves/conduits, tendons, fascia, dura, bone marrow, veins, arteries, cartilage, sperm, embryos, eggs, stem cells, cord blood, synthetic tissues (artificially prepared, human and non-human cellular-based products), and other cellular- and tissue-based transplant or implant products.

PROCEDURE:

1. The physician identifies the patient who is a candidate for the implantation or transplantation of Tissue and then notifies
    a. The Clinic Nurse, e.g. Cornea which is ordered by the Eye/ENT Clinic Staff
    b. The Operating Room Procurement Office, e.g. Allograft tissue for ACL procedures
2. In those instances in which tissue is being procured for a specific patient, the order must be entered into the Global Healthcare Exchange (GHX) Ordering System. The request for a Purchase Order (P.O.) must be uploaded into the GHX Ordering System.
    a. Contracted items – Will be automatically uploaded into GHX Ordering System including all necessary vendor information
    b. Non-Contracted items – Must be requested as a "Special Order"
3. The Supply Chain Operations will create and provide the company's representative (rep) with a Purchase Order.
4. Supply Chain Operations will verify the current licensure and/or Food and Drug Administration approval of the company from which the tissue is being ordered.
5. All testing of these tissues are done by the manufacturer prior to delivery.
6. If an adverse event occurs, including disease or other complications directly

related to the use of tissue, the patient(s) will be contacted utilizing the tracking log. The patient(s) will be brought back to the organization for evaluation.

7. The surgeon will identify the date of operation
8. The company's vendor/rep will be notified of the date of delivery (day of surgery). This notification will be done by the surgeon in the Clinic or the OR Procurement Office for all OR orders, as applicable.
9. Upon receipt of the product, Supply Chain Operations will notify the department to arrange a time for delivery of the product to the requesting clinical location.
10. The Tissue will be delivered to the receiving unit, packaged according to the manufacturer's recommendations
11. The product will be maintained in the refrigerator, as packaged
12. The product will be used in accordance with the manufacturer's instructions/specifications
13. At the time of use, the Tissue will be logged into a permanent log by Nursing, with an appropriate patient identifier for tracking purposes. The integrity of the package and the serial number(s) and Lot Number of the product must be included in the documentation.
    a. For all Tissue used in the Operating Room, this documentation will be recorded in SurgiNet, within the eMR.
    b. For all Tissue used in the Clinic, a permanent log book will be used to document the patient identifier for tracking purposes.
14. Should a need arise that would necessitate the product to be returned to the manufacturer; the OR Procurement Office or Nursing will repackage the product and contact Supply Chain Operations for pick-up.
15. If there is a request for either a product Recall or a need arises that would necessitate that the product be returned to the manufacturers, Supply Chain Operations will notify the company that their prior shipment is ready for pick-up to be returned to the factory of origin.
16. If there is product left over after the implantation or transplantation, it must be discarded in a bio-hazardous waste container, (red bag).

References: Joint Commission Provision of Care 17.10 and 17.20	
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