POLICY: MEDICAL DEVICE AND TISSUE TRACKING

CONTENT:

“The FDA defines a medical device as any instrument, apparatus, implant, in vitro reagent or other article that is used to prevent, diagnose, mitigate, or treat a disease or to affect the structure or function of the body, with the exception of drugs” (Medical Center Policy # 0165). The Safe Medical Devices Act of 1990 “requires that healthcare facilities track information on certain implantable and life-support devices and to report this information to manufacturers” (Medical Center Policy # 0165). In addition, The Joint Commission (TJC) recommends that healthcare facilities track information on tissue for medical use and report cases of suspected contamination or adverse effects to the source facility. The Office of Patient Safety and Risk Management coordinates any tissue look back/recall procedures identified internally or from the source facility. Procedures for acquisition, tracking, and storage of tissue must meet the standards defined by the Blood Bank and TJC.

1. Medical Devices subject to tracking under the Safe Medical Device Act are noted in the Medical Center Policy #0165. Tissues subject to tracking under TJC standards might include: bone, cornea, sclera, skin, heart valves/conduits, tendons, fascia, dura, bone marrow, veins, arteries, cartilage, synthetic tissue (artificially prepared, human and nonhuman based), and other cellular- and tissue-based transplant or implant products.

2. All ordering of medical devices is coordinated through the Implant Room of Surgical Supply. All ordering of tissues as outlined above is handled through the Implant Room. The Implant Room is responsible for and keeps validation information on each source facility. Storage locations for items ordered through the Implant Room, include:
   - the Implant Room, Omnicell units, or TrackCore for those items stored at room temperature, or
   - the Blood Bank for homograft valves and tissue stored using liquid nitrogen.

3. The Physical Plant monitors temperatures in locations where tissue is stored. If the temperature exceeds the established range the Implant Room is notified. The vendors for any effected issue are consulted as to the proper disposition of their tissue and to arrange replacement.

4. The Implant Room and the Blood Bank are responsible for monitoring and logging temperatures of items requiring refrigeration or freezing through an automated system (Systems Control). These units have functional alarms.

5. Autologous skin and skull flaps may be removed from a patient in the Operating Room (OR) and stored for later return to that patient. These items are stored by the

6. Blood Bank is responsible for maintaining temperature-monitoring logs. OR personnel are responsible for preparation and labeling of the item for dispersal to Blood Bank.

7. When an item is requested for re-implantation, OR personnel verify identification for the appropriate patient.

8. Cloned skin, if required for a specific patient, as determined by a physician, is purchased and all storage, processing, and handling are the responsibility of the company, who delivers it directly to the OR to the implanting physician.

9. Bone marrow harvest procedures may be performed in the Operating Room. OR personnel are responsible for appropriate labeling of harvested marrow. It is taken from the OR by and becomes the responsibility of the physician (Cancer Center Procedure Stem Cell Transplant (SCT) Program, Procedure #CL04.01 v1, “Bone Marrow Collection Procedure”; OR Procedure, Section C, “Bone Marrow Harvest”).

10. All FDA trackable devices are designated as such in CLINDOC, the computerized OR information system by a + after their description. When they are received, the Implant room is responsible for entering their serial number and date of receipt into the system as well as their storage location and status of “in stock”. Items stored in TrackCore are similarly entered into the TrackCore system and the TrackCore barcoded labels are placed on the items.

11. All tissue is designated as such in CLINDOC, with a ~ after their description.

12. When tissue items are received, the Implant Room is responsible for receipt, verification of package integrity, and verification that transport temperature range was controlled and acceptable. The information listed above, along with serial number, date of receipt, expiration date, and name of person who received it, are entered into the CLINDOC system and TrackCore, along with stock location and status of “in stock” by the Implant Room. Implant room works with Lifenet, BB and the TCV Manager to maintain inventory of cardiac homografts.

13. Items are removed from the Implant Room, Omnicell, TrackCore, or Nitrogen freezer in Blood Bank by the Implant Room staff or by the OR circulating nurse for delivery to an OR. Items removed from the Implant room must be logged out on the Implant Tracking Log by a SS staff member. Only the circulating nurse may present a product to the sterile field after performing a “Pause for a Cause” per OR Procedure, Section C, “Implant Verification”.
14. Items stored in Blood Bank are requested by the circulating nurse and transported to the Operating Room suite, using appropriate coolers and dry ice (preferable) or freezer packs to maintain appropriate temperatures. (Follow OR Procedure, Section C, “Homograft Valve/Tissue: Receipt and Retrieval of Grafts from Blood Bank Liquid Nitrogen Freezer”). Items located in freezers in Implant Room are requested by the circulating nurse and delivered by Implant Room staff, again using coolers and dry ice or freezer packs. Only the circulating nurse may present a product to the sterile field after performing a “Pause for a Cause” per OR Procedure, Section C, “Implant Verification”. The circulating nurse and the implanting physician are documented via the Intraoperative Record.

15. Tissue is handled and prepared for implantation per the source facility’s written instructions (package inserts).

16. The OR circulating nurse documents implantation of a trackable device or tissue via the Implant Screen of CLINDOC or via a manual implant record which is later keyed into CLINDOC. If a TrackCore sticker is on the item, it is to be scanned in the appropriate field in clindoc. This documentation encumbers the unique serial number of item and changes status to “implanted”, with the patient’s unique logged number attached. The Charge Capture group is responsible for any other status changes in CLINDOC.

17. Charge Capture personnel are responsible for reporting monthly to manufacturers and tissue source facilities, the status and detailed implantation and explanation information for these designated items. Electronic copies of these reports are kept by the Charge Capture personnel for review. This disclosure of patient information is reported to the HIPAA office of HIS.

18. Records that document the designated item’s source facility, the original donor and lot number (unique serial number), all recipients or other disposition of the tissue, and expiration dates, are retained for a minimum of ten years beyond date of distribution, transplantation, disposition, or expiration of tissue.

19. Device and tissue tracking is per the guidelines outlined in Medical Center Policies #0165 and #0019.

20. Product problems with tissue should be reported via a Be Safe Report. Examples of problems to report include: packaging, labeling, irregularity, damage, sterility issues, temperature issues, surgical difficulty with transplantation, or for any other reason a tissue might be discarded. These Be Safe Reports may be completed by the person receiving the tissue who discovers a problem with receipt or by the clinician who discovers the problem at time of opening/use.

21. If there is any suspected reaction to implanted tissue/implant (including explantation), the Office of Risk Management is notified for further follow-up action.
22. In the case of a tissue or device recall, the Office of Risk Management is immediately notified and oversees the recall/look back process.

REFERENCE:

UVA Health System Policy #0019 “Alerts and Recalls of Products, Tissues Devices and Drugs”
UVA Health System Policy #0165 "Medical Device Failures and Safe Medical Devices Act Reporting"
Surgical Services Policy #609 “Receipt, Storage, and Dispersal of Trackable and Non-Trackable Implants and Tissue”
OR Procedure, Section C “Allograft Valve Retrieval”
OR Procedure, Section C “Allograft Freeze Dried Tissue (Bone) Procuring and Reconstituting”
OR Procedure, Section C “Bone Flap Preservation and Retrieval”
OR Procedure, Section C “AlloDerm and Allograft Skin”
OR Procedure, Section C “Sclera and Cornea”
OR Procedure, Section C “Implant Verification”
OR Procedure, Section G “Perioperative Record Documentation”
OR Procedure, Section G “Implant Usage and Charge Capture”
OR Procedure, Section C, “Bone Marrow Harvest”
Cancer Center Procedure, Stem Cell Transplant (SCT) Program, Procedure #CL04.01 v1, “Bone Marrow Collection Procedure”
Medical Laboratories Procedure “Explants, Malfunctioning Medical Devices for Return to the Vendor”

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