**Purpose:**

Define the different types of non-conforming autologous bone. Describe process of evaluation, transport, storage and release of non-conforming autologous bone.

**Policy:**

Transfusion Services adheres to current good tissue practices (cGTP) for the acceptance, storage and distribution of autologous bone. These include defining the conditions that must be met for a product to be accepted, stored and released. These are irreplaceable specimens. A product not meeting cGTP may still be released with the approval of a Medical Director (TSL) and Attending Physician.

**Procedure:**

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| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| **Non-conforming Definition:** The Autologous Bone is Non-Conforming if any of the following applies: |
| **Culture Results** | * Result of 7 day microbial product culture is **pending**.
* Result of 7 day microbial product culture is **positive**.
 |  |
| **Packaging and Source** | * Any damage or loss of integrity to the packaged product, either before or after receipt.
* Out of monitored storage for more than 20 minutes.
* Any product received from an outside facility, other than the University of Washington Medical Center
 |  |
| **Storage** | * Temperature failure of an ultra-low freezer used for autologous bone storage.
 |  |
| **Labeling** | * Demographics changes following labeling of bone package remain unresolved:
 |  |

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| **Storage of Non-Conforming Bone Packages** |
| **Storage of Non-conforming Bone in TSL** | * Non-conforming bone packages will be stored separate from regular inventory
* Immediately upon identifying a bone package is non-conforming, move:
* Positive Cultures: QUARANTINE bin
* Other non-conforming bone packages: QUARANTINE bin
 | **Receipt and Storage of Autologous Bone** |

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| **Step** | **Action** | **Related Documents** |
| **Processing Non-conforming Autologous Bone** |
| **Pending Culture Results** | * Complete a Release of a Non-Conforming Autologous Bone form.
* The Attending Physician must sign it prior to release of the packaged product.
* Once the product has been issued forward the signed Non-Conforming form to the Medical Director for review.
 | Issuing Autologous Bone |
| **Positive Culture Results** | * Prepare culture report and Release of Non-conforming Autologous form per Autologous Bone Maintenance procedure
* The Attending Physician must sign prior to release of the packaged product.
* Once the product has been issued, staple the *signed /completed* Non-conforming Product Release form with culture report and forward to Medical Director for review.
 | Autologous Bone MaintenanceAutologous Tissue Tracking LogReceipt and Storage of Autologous Bone |
| **Fails Visual Inspection Upon Receipt** | * Do not accept the package.
* Return the bone package to the OR immediately.
* *Note: If decision is made to accept the package, complete a QIM and PSN.*
* *Complete an SOP deviation form*
 | PSN reportingQI report formSOP deviation form |
| **Damaged during Storage** | * If the envelope becomes unsealed or develops any holes or tears during storage:
* Complete a QIM and a PSN.
* Quarantine bone package:
	+ Attach Quarantine Card
	+ Store in Quarantine bin
* Notify the Attending Physician and TSL Medical Director Immediately.
 |  |
| **Patient Demographics Do Not Match** | **During Storage*** Processed per Autologous Bone Maintenance procedure

**At Issue:*** Request SQ update, if appropriate
* Print the Epic/ORCA patient demographics screen and attach to the Tissue Tracking Record
* Verify against all documentation before release of product.
* Request signature of physician on a Release of Non-conforming Product form
* Complete a QIM and PSN.
 | Autologous Bone MaintenanceUpdating Patient Demographics in Sunquest to Match EPIC Registration ChangesPSN reportingQI report formSOP deviation form |

|  |  |  |
| --- | --- | --- |
| **Step** | **Action** | **Related Documents** |
| **Processing Non-conforming Autologous Bone** |
| **Out of Monitored storage for more than 20 minute** | * Store in QUARANTINE bin
* Intent of re-implantation after tissue has been out of monitored refrigeration should be confirmed : If
 | Discard of Autologous Bone |
| Yes | No |
| * Complete a release of a Non-conforming Autologous Bone form at re-issue
* The Attending physician must sign the form prior to release of the returned product
 | * Initiate Discard procedure
 |
| **Storage** | If one of the ultra-low freezers fails to maintain normal temperature range:1. Remove all products from unit to the back-up as quickly as possible.
2. Complete a QIM.
3. Notify engineering and complete a work order.
 | Responding to Temperature AlarmsUsing Temp Trak SystemRemoving Equipment from Service |
| **Facility Policy** | * Any acceptance of autologous bone **NOT** processed by HMC or UWMC and other affiliated facility will require a signed deviation form from the TSL Medical Directors and will be issued as a non-conforming product.
 | Autologous Bone Process |

**References**

Standards for Tissue Banking, Current edition, American Association for Tissue Banks, AATB, Bethesda, MD.