**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 Maintenance  Autologous Tissue Tracking Log  Receipt 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 reporting  QI report form  SOP 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 Maintenance  Updating Patient Demographics in Sunquest to Match EPIC Registration Changes  PSN reporting  QI report form  SOP deviation form |

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| **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 Alarms  Using Temp Trak System  Removing 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.