**Purpose:**

Provide instructions for issuing for re-implantation and return of issued Autologous Bone to TSL.

**Procedure:**

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| **Step** | **Action** | **Related Documents** |
| **OR Staff** | * Provides notification of intent to re-implant product (e.g. phone call or Tissue Release Form). * Must arrive in TSL with Tissue Release Form. * Participates in two person “read-back” of patient identifiers on Tissue Release Form and bone package label. | Tissue Release Form |

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| **TSL Staff** | | |
| **Surgery Schedule Review by Night Shift** | * Review the daily surgery schedule for potential re-implantations * ***Note:*** *Patient may have multiple bone packages* * For potential procedures, search alphabetically for the Tissue Tracking Record in the Tissue Tracking Binders. * **Front of 1st Notebook**: Positive/Quarantine/Pending/To Be Discarded * **Inventory**: Divided into multiple notebooks by last name * Locate the patient on the Autologous Tissue Tracking Log by ID number. * *If a patient has a* ***Release of Non-Conforming form*** *attached to the Tissue Tracking Record, it must be signed by the Attending Physician prior to issuing the bone package.* * Post documents on the CLT area whiteboard * Note information on the CLT Shift Hand Off form. | CLT Shift Hand Off Form  Tissue Tracking Record  Autologous Tissue Tracking Log  Release of Non-Conforming Autologous Tissue form |
| **Issue** | | |
| **Visual Inspection** | * Perform visual inspection of the bone package. | Receipt and Storage of Autologous Bone |
| **Read Back** | * Perform read back: (TSL and OR Personnel fill either role) * **Reader:** Read the patient’s MRN and name from the patient label on the Cryo Label * **Listener:** Verify the patient information on the Tissue Tracking Record and Tissue Release Form |  |

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| **Issue (continued)** | | |
| **Step** | **Action** | **Related Documents** |
| **Bone Release Form** | * On the Tissue Release Form, “To be completed by TSL” section: * Record Visual Inspection * Record the Bone Sample ID Number * Record Tech ID for two person verification. | Tissue Release Form |
| **Autologous Tissue Tracking Log** | * Complete the Autologous Tissue Tracking Log: * Date/Time and Tech ID in the “Removed from the Freezer” column. * The OR Personnel accepting the package will sign in the “Issued To” column | Autologous Tissue Tracking Log |
| **Implantation Warning Slip** | Time Stamp and rubber band an implantation warning slip to the package. | Implantation Warning Slip |
| **Release** | Release bone package and Tissue Release form to the OR personnel after verifying all information has been completed. |  |
| **File Tissue Tracking Record** | Attach a copy of the Tissue Release form to the Tissue Tracking Record and file in the Tissue Tracking Issue Binder alphabetically. | Tissue Tracking Record |
| ***No Autologous Bone products will be delivered to O.R. by TSL staff.*** | | |

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| **Returned Product** | | |
| **Implantation Warning Slip** | * Timestamp upon return * Determine time bone package has been in O.R. * Based on elapsed time, proceed below. |  |
| **Within 20 Minutes** | * Inspect bone package for integrity and clear labeling. * Ensure the envelope is completely sealed. * Check for any holes, tears or damage to the envelope. * Patient information written on the package must be legible and match the patient label. * Update the Autologous Tissue Tracking Log as   + “Returned to inventory” with the Date/Time and Tech ID.   + Check storage bin location * Replace bone package back in the appropriate bin in numerical order. * File Tissue Tracking Record in Tissue Tracking Records Binder alphabetically. | Autologous Tissue Tracking Log  Tissue Tracking Record |

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| **Step** | **Action** | **Related Documents** |
| **Receipt of Returned Product** | | |
| **Out of Monitored Storage >20 Minutes** | * Ask OR staff if re-implantation is anticipated and note response on Quarantine slip. * Record time out of monitored storage on the Non-Conforming Tissue Form. * Time stamp quarantine slip, rubber-band it and the Implantation slip to package; place in Quarantine * On the Autologous Tissue Tracking Log, in the Quarantine section, note Date/Time tissue was returned. * Complete a Release of Non-Conforming Autologous Tissue Form and print two copies. * Place one copy of the Non-Conforming form on top of the Tracking Record, and file in the Quarantine/Pending section of the Tissue Tracking Binder. * Attach a copy of the Non-Conforming form with a copy of the Tissue Tracking Record; forward to Medical Director for review. * Once the Medical Director has determined the outcome of the product, replace the unsigned copy for the signed. *(Note: If the product is deemed unusable proceed to discard procedure.)* | Quarantine Slip  Release of Non-Conforming Autologous Tissue Form  Autologous Tissue Tracking Log  Discarding Autologous Bone |

**References:**

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

Bethesda, MD.