**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 FormTissue Tracking RecordAutologous Tissue Tracking LogRelease 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.
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| **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 LogTissue 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 SlipRelease of Non-Conforming Autologous Tissue FormAutologous Tissue Tracking LogDiscarding Autologous Bone |

**References:**

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

Bethesda, MD.