

SECTION: Clinical ID NO.: CPI-9-530 PAGE: 1 of 6 ISSUE DATE: June 19, 2017 ISSUE.REVISION: 1.1 REVISION DATE: July 26, 2023 APPROVED BY: Tissue Authority

# **Clinical Process Instruction Manual**

## **Osteochondral Recovery Process Instruction**

### **Policy:**

Multi Tissue Recovery Coordinators (MTRC) are responsible for carrying out procedures for the recovery, packaging, labeling, and shipping of donated osteochondral tissue and all related documentation. Recovered tissue is transported to, and all pertinent documentation is shared with, the accepting tissue bank for processing and determination of final tissue disposition.

Osteochondral tissue is recovered on a case-by-case basis, from donors between the ages of 16 - 40 years.

Osteochondral tissue shall be recovered "en bloc," which means no violation of the capsule. Instead the whole joint is recovered by removing soft tissue from above and below the joint.

#### **Process:**

#### General

- 1. Compliance with the following principals shall apply to osteochondral tissue recovery:
  - 1.1. Recovery of tissue shall be performed in an operating room, or pre-approved designated site such as the coroner's recovery suite.
  - 1.2. All tissue shall be recovered under sterile conditions, employing aseptic surgical techniques.
  - 1.3. Access to, and movement in and out of the recovery suite will be limited during osteochondral recovery.
  - 1.4. Tissue recovery procedures shall not occur after embalming procedures have begun.
  - 1.5. Tissue shall be recovered from only one donor at a time within the same recovery suite.
  - 1.6. All recovery staff shall follow routine practices and shall wear Personal Protective Equipment (PPE) in addition to surgical attire when in contact with the donor. See *CPI-9-1504 Routine Practices and Personal Protective Equipment Process Instruction.*
  - 1.7. Osteochondral recovery surgical preparation shall commence within 24 hours of asystole, provided the body was refrigerated within 12 hours of asystole. Osteochondral recovery shall commence within 15 hours of asystole if the donor has not been refrigerated. See On-Site Medical Records Review for Multi-tissue Recovery Process Instruction, CPI-9-263.



SECTION: Clinical ID NO.: CPI-9-530 PAGE: 2 of 6 ISSUE DATE: June 19, 2017 ISSUE.REVISION: 1.1 REVISION DATE: July 26, 2023 APPROVED BY: Tissue Authority

# **Clinical Process Instruction Manual**

## **Osteochondral Recovery Process Instruction**

- 1.8. There should be at least two sterile MTRCs scrubbed in for the osteochondral recovery procedure. The circulator is responsible for set up and documentation of the procedure as assigned.
- 1.9. Osteochondral tissue should not be recovered from areas with open fractures, deep lacerations, avulsions, recent operative sites, or any open skin wound grossly contaminated with dirt or debris.

### Recovery of Osteochondral Tissue

2. Refer to CPI-9-524 Tissue Recovery Sequencing and Zoning for order of recovery.

#### Whole Shoulder

- 3. The procedure starts by making an anterior incision from mid clavicle to distal mid arm.
- 4. The plane of dissection is between subcutaneous tissue and the superficial fascia.
- 5. Minimize cutting through muscles during initial incision in order to avoid any contact with the shoulder joint.
- 6. Dissect tissue around the clavicle and mid humerus to expose the bone circumferentially, taking care not to violate the integrity of the capsule.
- 7. The next step is transverse cut of the clavicle, then the humerus 4 5 cm below the shoulder joint; finial dissection is proximally through the scapular neck, medial to the acromion joint.
- 8. The fresh shoulder graft is removed as one piece with the shoulder joint surrounded by intact soft tissue, except for skin and subcutaneous tissue.
- 9. A swab must be taken of the graft surface for bacterial culturing. For instructions on how to swab en bloc tissues, refer to *CPI-9-559 Recovery Cultures*.
- 10. Exposed bone must be wrapped with a sterile sponge or towel, the whole graft should then be wrapped securely in a sterile towel.



SECTION: Clinical ID NO.: CPI-9-530 PAGE: **3** of 6 ISSUE DATE: June 19, 2017 ISSUE.REVISION: 1.1 REVISION DATE: July 26, 2023 APPROVED BY: Tissue Authority

# **Clinical Process Instruction Manual**

# **Osteochondral Recovery Process Instruction**

11. The graft is submerged in the packaging solution of Ringer's Lactate reconstituted with Cefazolin (1 g/L) and Bacitracin (50,000 U/L). Two (2) liters of Ringer's Lactate and reconstituted antibiotics will be used for each graft.

## Whole Elbow

- 12. The procedure should start by making an anterior incision from distal upper arm to approximately 4 inches above the medial wrist.
- 13. The plane of dissection is between subcutaneous tissue and the superficial fascia.
- 14. Minimize cutting through muscles during the initial incision in order to avoid any contact with the elbow joint.
- 15. Dissect tissue 4 5 cm above and bellow the elbow to expose the bone circumferentially.
- 16. The next step is transverse cut of the humerus 4 5 cm above the elbow joint and a transverse cut of both the radius and ulna, 4 5 cm below the elbow.
- 17. The fresh elbow graft is removed as one piece with the elbow joint surrounded by intact soft tissue, except for skin and subcutaneous tissue.
- 18. A swab must be taken of the graft surface for bacterial culturing. For instructions on how to swab en bloc tissues, refer to *CPI-9-559 Recovery Cultures*.
- 19. Exposed bone must be wrapped with a sterile sponge or towel, the whole graft should then be wrapped securely in a sterile towel.
- 20. The graft is submerged in the packaging solution of Ringer's Lactate reconstituted with Cefazolin (1 g/L) and Bacitracin (50,000 U/L). Two (2) liters of Ringer's Lactate and reconstituted antibiotics will be used for each graft.

### Whole Knee

21. The procedure starts by making a middle line incision from upper anterior third of the thigh to distal anterior part of the leg.



SECTION: Clinical ID NO.: CPI-9-530 PAGE: **4** of 6 ISSUE DATE: June 19, 2017 ISSUE.REVISION: 1.1 REVISION DATE: July 26, 2023 APPROVED BY: Tissue Authority

# **Clinical Process Instruction Manual**

# **Osteochondral Recovery Process Instruction**

- 22. The plane of dissection is between subcutaneous tissue and the superficial fascia.
- 23. Minimize cutting through muscles during the initial incision in order to avoid any contact with the knee joint.
- 24. Dissect tissue 4 5 cm above and bellow the knee to expose the bone circumferentially.
- 25. The next step is a transverse cut through femoral bone 4 5 cm above the patella and cut through tibia and fibula bones 4 5 cm below the tibial tuberosity.
- 26. The fresh knee graft is removed as one piece with knee joint surrounded by intact soft tissue, except for skin and subcutaneous tissue.
- 27. A swab must be taken of the graft surface for bacterial culturing. For instructions on how to swab en bloc tissues, refer to *CPI-9-559 Recovery Cultures*.
- 28. Exposed bone must be wrapped with a sterile sponge or towel, the whole graft should then be wrapped securely in a sterile towel.
- 29. The graft is submerged in the packaging solution of Ringer's Lactate reconstituted with Cefazolin (1 g/L) and Bacitracin (50,000 U/L). Two (2) liters of Ringer's Lactate and reconstituted antibiotics will be used for each graft.

### Whole Ankle

- 30. The procedure starts by making a middle line incision from upper anterior third of the leg to distal anterior part of the foot.
- 31. The plane of dissection is between subcutaneous tissue and the superficial fascia. Minimize cutting through muscles during the initial incision in order to avoid any contact with the ankle joint.
- 32. Dissect tissue 4 5 cm bellow the knee to expose the bone circumferentially.
- 33. The next step is transverse cut through tibia and fibula bones at least 4 5 cm above the ankle joint and distally through Lisfranc joint.
- 34. The fresh ankle graft is removed as one piece with the ankle joint surrounded by intact soft tissue, except for skin and subcutaneous tissue.



SECTION: Clinical ID NO.: CPI-9-530 PAGE: **5** of 6 ISSUE DATE: June 19, 2017 ISSUE.REVISION: 1.1 REVISION DATE: July 26, 2023 APPROVED BY: Tissue Authority

# **Clinical Process Instruction Manual**

# **Osteochondral Recovery Process Instruction**

- 35. A swab must be taken of the graft surface for bacterial culturing. For instructions on how to swab en bloc tissues, refer to *CPI-9-559 Recovery Cultures*.
- 36. Exposed bone must be wrapped with a sterile sponge or towel, the whole graft should then be wrapped securely in a sterile towel.
- 37. The graft is submerged in the packaging solution of Ringer's Lactate reconstituted with Cefazolin (1 g/L) and Bacitracin (50,000 U/L). Two (2) liters of Ringer's Lactate and reconstituted antibiotics will be used for each graft.

### Post-Recovery Packaging Fresh Osteoarticular (MSAT)

- 38. Grafts shall be packaged in Ringer's lactate with Cefazolin (1 g/L) and Bacitracin (50,000 U/L).
  - 37.1 Wipe needle port on Ringer's Lactate bag and antibiotic vials with alcohol swab. Using a sterile syringe and a pair of forceps (to hold the port) withdraw 15 mL of Ringer's Lactate out of bag. Insert 5 10 mL of Ringer's Lactate into each antibiotic vial. Discard needle. Mix antibiotics and Ringer's Lactate together by rolling vials in hands. Wipe insertion on bag with a alcohol swab. Use the syringe and new needle to withdraw both antibiotics out of each vial into the same syringe. Discard needle. Using a pair of forceps (to hold the port), a syringe and new needle, inject antibiotics back into bag of Ringer's Lactate.
- 39. The following steps must be followed:
  - 39.1. Fill the sterile plastic bag with 2000 mL sterile Ringer's Lactate and reconstituted antibiotics and place the tissues directly into this solution. Secure the packaging by twisting and knotting the bag.
  - 39.2. Place the bag with tissue inside a second sterile bag then label and secure the bag by twisting and knotting it. The tissue is then placed inside a third sterile bag and is secured by twisting the bag, goose necking the twist and securing with a zip tie.
- 40. Recovery documentation shall be completed, including any problems or incidents that occurred during the procedure in iTransplant or in the Tissue Recovery Form (CSF-9-146) if applicable.
- 41. A completed and signed Recovered Bone Tissue Package Insert (CSF-9-149) and Recovered Musculoskeletal Transplant Label- MSAT (CSF-9-152) must accompany the tissue during transport. A copy shall be included in the donor chart.



SECTION: Clinical ID NO.: CPI-9-530 PAGE: **6** of 6 ISSUE DATE: June 19, 2017 ISSUE.REVISION: 1.1 REVISION DATE: July 26, 2023 APPROVED BY: Tissue Authority

# **Clinical Process Instruction Manual**

## **Osteochondral Recovery Process Instruction**

### **Tissue Transportation**

- 42. Osteochondral tissue is to be transported to Mount Sinai Allograft Technologies (MSAT) in a validated transport cooler separate from other musculoskeletal tissues.
- 43. The cooler has been packed with a sufficient amount of ice in order to maintain a temperature of 0°C 10°C.
- 44. Upon arrival to MSAT, the osteochondral tissue is placed in the recovery refrigerator.
- 45. The fresh osteochondral tissue is good for up to 14 days when stored at 1°C 10°C with a maximum of two solution changes during 4 7 days cycle.

#### **Records:**

No records

### **References:**

- Multi-Tissue Recovery Form
- Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. D5.300, D5.400, D5.500, D5.520, D5.530, D5.600
- Recovered Bone Tissue Package Insert (CSF-9-149)
- Recovered Musculoskeletal Transplant Label- MSAT (CSF-9-152)
- *Multi-Tissue Recovery Note (*CSF-9-147)