

PROCEDURE FOR: Tissue Autografts - Cranial Flap Bone Banking for Internal Use

- POLICY:
1. Cranial bone flap autografts will be recovered, processed, stored and transplanted / reimplanted in a manner that minimizes microbial growth, reduces the risk of errors and meets guidelines established by the American Association of Tissue Banks (AATB) and Food and Drug Administration (FDA) guidelines.
 2. Aerobic and anaerobic tissue cultures will be collected when the bone is retrieved; the attending surgeon will be notified of any positive culture and the bone will be destroyed in accordance with state and federal regulations as biohazardous material.
 3. The selected package or container for storing the bone will provide an adequate barrier to microbial contamination, will be compatible with the desired type of preservation and storage conditions, and will be impervious to moisture.
 4. The selected package or container will be labeled "For Autologous Use Only" and according to established procedure.
 5. Autografts will be stored in the temperature-controlled, monitored OR tissue freezer in a specifically labeled bin for cranial bone flap autografts for a maximum of 6 months. The Blood Bank will be the back-up storage location should the monitored freezer fail.
 6. Autografts will be released only to the donor for transplantation / reimplantation and pending confirmation that all processing, labeling and storage criteria have been reviewed and deemed satisfactory. Tissue that does not meet release criteria will be destroyed.
 7. The attending surgeon will indicate the desire to transplant / reimplant autologous bone flap at the time of the booking, if possible, and during the procedure at the latest. Informed consent will be obtained for the transplantation / reimplantation.
 8. When the flap is obtained and again when the flap is reimplanted, the nurse will enter a note in the patient record to describe that the patient's own tissue is used for the autograft and that hospital policy was followed.
 9. An autograft quality management program will be conducted with the intention to prevent the introduction, transmission or spread of communicable disease and to evaluate the structure, processes and outcome of the autograft tissue-banking program.
 10. In accordance with "Freezer Maintenance and Operation" section of the procedure for: Tissue Allograft, temperature monitoring will be ongoing through the hardwired connection with the Environmental Control Center (ECC). Also per this procedure, OR Materials Management personnel will routinely inventory and defrost the freezer, and will test the freezer quarterly for temperature alarm function.
 11. Adverse reactions to autografts will be reported in accordance with the Safe Medical Devices Act. Adverse reactions to non-device tissue implants, such as transmission of disease via tissue graft, unanticipated graft failure, or other fatal or adverse reactions

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arising from the receipt of tissues will be done according to current FDA regulations.

12. Records maintenance of tracking log sheets will be the responsibility of Materials Management.

13. Overall authority, accountability and responsibility of the tissue autograft-handling program belongs to the Department of Nursing. Quality monitoring and maintenance of storage equipment belongs to Materials Management staff in the Operating Room.

PROCEDURE: Autograft Acquisition Procedure

<u>Action</u>	<u>Points of Emphasis</u>
1. Collect aerobic and anaerobic tissue cultures when the bone is retrieved and designated for banking.	1. Transplanting contaminated tissue has resulted in transmission of viral, bacterial and fungal infections.
2. Transfer bone immediately using aseptic technique to a sterile storage container. a. obtain cranial bone flap autograft kit from neurosurgery section in main OR storage room; b. introduce scrub portion of kit to sterile field (2 sterile specimen bags); c. scrub person will insert flap into first sterile specimen bag, extrude air, seal; repeat with second specimen bag; pass off field to circulator d. circulator will label unsterile rigid container with pre-printed label as identified in next portion of procedure.	2.

PROCEDURE: Autograft Labeling Procedure

<u>Action</u>	<u>Points of Emphasis</u>
1. The label for the autograft package / storage container will include the following information: a. two pre-printed unique patient identifiers, including name and medical record number (T0#). b. clear description of the tissue as a Cranial Bone Flap Autograft; c. recovery date; d. expiration date of no greater than 6 months from the date of collection, including month and year; e. a note indicating whether the tissue was recovered under aseptic conditions; f. a label indicating <i>Evaluation for Infectious Substances Pending</i> until	

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the microbiology report is received and the flap either is cleared for continued storage or is found to harbor microorganisms and must be discarded.

2. Label the package clearly to indicate *"For Autologous Use Only"*.
 3. Using a sharpie marker, circulator will label the rigid plastic container with:
 - a. patient name and medical record number;
 - b. recovery date;
 - c. description of "Cranial Bone Flap Autograft".
 4. Enclose rigid container in outer clear plastic bag.
 5. Once the microbiology biology report has been received:
 - a. if positive, notify surgeon and discard autograft as biohazardous material; or
 - b. if negative, print copy of microbiology report, remove *Pending* sticker and enclose microbiology report with bagged autograft container.
2. Autografts should be labeled differently from allografts to minimize the risk of error.
 3. Sticker adhesive will not remain intact and container must retain some identifying data at all times.

PROCEDURE: Autograft Storage and Tracking

Action

Points of Emphasis

1. Complete Cranial Bone Flap Autograft tracking record.
 - a. top copy stays with flap;
 - b. back copy goes to Materials Management.
 2. Contain and freeze autologous bone flaps as soon as possible after recovery.
 2. Store autologous bone flaps in separately labeled bin in designated tissue freezer.
 3. Store autologous bone flaps so that expiration date is clearly visible.
 4. Materials Management staff will notify nursing about autologous bone flaps stored longer than 6 months.
1. Tracking record is needed to comply with guidelines and regulations.
 3. Autografts should be stored separately from allografts to minimize the risk of error.
 4. Safe duration of autograft storage is defined as 6 months and tissue must be destroyed per regulations for biohazardous material.
 - 5.

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5. Nursing will notify the attending surgeon regarding destruction of any autologous bone flap prior to doing so.

PROCEDURE: Criteria for Verification and Release of Autologous Bone Flaps

<u>Action</u>	<u>Points of Emphasis</u>
1. The circulating nurse will confirm the need for any autologous bone flap during implementation of the Universal Protocol prior to the start of the procedure.	1. Verification should include correct procedure, site, position and implants for the correct patient.
2. Obtain any autologous bone flap from the separately labeled freezer shelf.	
3. Prior to leaving the freezer area, verify that the intended recipient of the autologous bone flap is the donor.	3. Use two unique identifiers.
4. Prior to introducing any autologous bone flap to the sterile field, verify with the surgeon the contents of the package, expiration date and any other pertinent information.	
6. Introduce flap to sterile field as follows: a. circulator will remove outer wrap from around rigid plastic container; b. circulator will open rigid container and remove inner plastic bags from container; c. circulator will peel outer of two inner bags outward and downward, being careful not to contaminate inner plastic bag; d. scrub person will extract inner bag with flap and place on sterile field, then remove flap.	
7. Complete Flap Release / Reimplantation section of Tracking Log Sheet and submit to Materials Management for retention.	

APPROVAL: Nursing Standards Committee

EFFECTIVE DATE: 7/06

REVIEWED DATES: 7/09