UJMTB
UNIVERSITY OF MIAMI TISSUE BANK

HUMAN FREEZE-DRIED ALLOGRAFT

QUALITY ASSURANCE STATEMENT AND PREPARATION FOR USE

The enclosed tissue is for single patient use only.

There is no charge for the tissue. Accompanying charges cover excision and processing expenses.

The enclosed donated human-tissue allograft supplied by the University of Miami Tissue Bank is for use by, or on order for, a licensed physician. The tissue was recovered and processed aseptically, following rigorous and technical quality assurance standards, in a controlled environment. The donor and donor tissue have been subjected to extensive biological and medical screening to guard against the possibility of recipient exposure to, or transmission of, infectious processes such as HIV, Hepatitis, or exclusionary medical conditions. These screening procedures are performed in accordance with standards, regulations, statutes and/or directives of the American Association of Tissue Banks (AATB)[1], the U.S. Food and Drug Administration (FDA)[2], State Licensing Agencies[3,4,5,6,7], the European Union[9] and Health Canada[10]. Additional infectious disease testing and screening in excess of the requirements by the AATB and FDA may have been completed. Data has been reviewed by a Medical Director or Associate Medical Director (licensed physician) of the University of Miami Tissue Bank and the allograft has been deemed suitable for transplantation.

1. A qualified donor blood sample was tested using test kits licensed (if available) for donor screening by a laboratory certified/registered to perform such testing in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and FDA. All required **infectious disease tests** listed below were found to be **nonreactive or negative**.

TEST	SYMBOL
-Human Immunodeficiency Virus (HIV)	
HIV-1/2 Antibodies	HIV-1/2-Ab
Nucleic Acid Test for HIV-1 RNA	HIV-1 NAT
-Hepatitis B Virus (HBV)	
HBV Surface Antigen	HBsAg
HBV Core Antibody (IgG & IgM)	HBcAb
Nucleic Acid Test for HBV DNA (if applicable)	HBV NAT
-Hepatitis C Virus (HCV)	
HCV Antibody	HCVAb
Nucleic Acid Test for HCV RNA	HCV NAT
-Human T Cell Lymphotrophic Virus I/II (if applicable)	
HTLV-I/II Antibody	HTLV-I/II-Ab
-Syphilis – Rapid Plasma Reagin Screen	RPR*
Or	
T. Pallidum IgG	T. pallidum IgG

*Tissues from a donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, are cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

2. Non-required screening tests for exposure to other viruses or parasites such as those listed below may have been completed on the donor by other agencies involved in the donation process. A negative/nonreactive result is not required for these tests; however, all donors are evaluated on a case-by-case basis by the Medical Director or Associate Medical Director.

-Cytomegalovirus	CMV Ab (IgG & IgM)
-Epstein Barr Virus	EBV Ab (IgG & IgM)
-Toxoplasma gondii	Toxoplasma Ab (IgG & IgM)
-Trypanosoma cruzi	T. cruzi Ab (IgG & IgM)

3. Over 90% of the donors undergo additional medical evaluation and screening for non-specific infections, malignancies and exclusionary medical conditions via autopsies performed by a licensed pathologist.
4. The accompanying allograft has been subjected to extensive **microbiologic studies** at each phase of development: recovery, processing, and final packaging.
5. Allografts labeled with "IRRD" have been exposed to gamma radiation for secondary sterilization at a dosage range of 2.5 to 3.8 megarads (25-38 kGy) [bone allografts] and 1.5 to 2.5 megarads (15 -25 kGy) [soft tissue allografts]. Post irradiation, the allograft may have been exposed to hydrogen peroxide solution followed by immersion in sterile water.
6. Allografts labeled with "ETO" have been exposed to ethylene oxide gas for secondary sterilization and subsequent diffusion process for the elimination of sterilant residuals. A representative allograft has been tested and determined to contain sterilant residuals below the acceptable limits established by the AATB.
7. Allografts labeled with "DEMIN" have been subjected to a demineralization process by exposure to Hydrochloric Acid and Phosphate Buffer solutions.
8. OsteoAMP allografts have been exposed to Acetic Acid, Hydrochloric Acid, Hydrogen Peroxide and Phosphate Buffer solutions during processing.
9. There are no known contraindications.

The tissue was exposed to Gentamicin and either Vancomycin or Bacitracin. Although the tissue was rinsed with sterile saline and (or) sterile water throughout processing, traces of the antibiotics, Hydrochloric Acid, Peracetic Acid, Acetic Acetic Acid, Hydrogen Peroxide, Brij 35, and Phosphate Buffer solutions (applicable to demineralized grafts, dermis grafts, and/or OsteoAMP grafts) may remain in the tissue. Individuals with known sensitivities to any of these agents should not receive this allograft.

The allograft may have come in contact with latex gloves during processing which may cause an allergic reaction.

Although all efforts have been made to ensure the safety of the allograft, current technologies may not preclude the transmission of all diseases.

Any adverse outcomes potentially attributable to the tissue must be reported immediately to the University of Miami Tissue Bank at the telephone number indicated below.

OVER

UNIVERSITY OF MIAMI TISSUE BANK
1951 N.W. 7TH AVENUE, SUITE 200, MIAMI, FLORIDA USA 33136
TEL: (888) 684-7783 (305) 356-0900

STORAGE REQUIREMENTS AND PREPARATION FOR USE OF FREEZE DRIED ALLOGRAFT

The allograft has been freeze-dried, sealed in its packaging container, and must be stored at room temperature. The allograft must be reconstituted prior to implantation. Rehydration time varies with the type of allograft. Reconstitute large bone allografts that are to be sawed, drilled, or shaped for a minimum of 12 hours; weight bearing allografts (tri-cortical blocks, segments, struts, dowels, etc.) for 2-4 hours; and crushed bone and soft tissue allografts for less than or equal to one hour prior to implantation. Bone allografts must not be brittle and soft tissue allografts (fascia lata, tendons, etc.) must be soft and entirely pliable prior to implantation. *Once the package seal is broken, the allograft must be reconstituted and used within 24 hours.*

The allograft was processed and packaged aseptically and must be handled in an aseptic manner to prevent contamination.

DO NOT USE IF PACKAGE INTEGRITY HAS BEEN COMPROMISED.

ONCE THE USER BREAKS THE SEAL, THE GRAFT MUST BE TRANSPLANTED (if appropriate) OR DISCARDED.

INSTRUCTIONS FOR USE

If packaged in two-layer pouch configuration:

The allograft is aseptically packaged in one tear-pouch and one peel pouch and secured in a box to ensure allograft integrity.
THE INNER POUCH IS CONSIDERED STERILE.

Step 1: Remove the graft from the box packaging.
Step 2: Utilizing sterile technique, peel open the peel pouch from the chevron end and present the inner pouch to the sterile field.
Step 3: Locate the tear notch on the pouch, and tear open. Place the graft in a basin.
Step 4: Pour sterile solution of choice into the basin until the allograft is completely immersed in solution. Antibiotics of the physician's preference may be added to the solution. After the prescribed reconstitution time, the allograft is now ready for use.
Step 5: If the allograft is to remain in solution for more than 2 hours, the graft must be stored in the refrigerator at 1 to 10°C until the time of surgery. Before placing the graft in cold storage, ensure the rim of the basin is dry and cover and seal the basin with a sterile Vi-Drape or similar adhesive drape. Double wrap the sealed basin with sterile waterproof wrappers.

If packaged in three-layer pouch configuration:

The allograft is aseptically packaged in one barrier bag and two peel pouches and secured in a box to ensure allograft integrity.
THE INNER BAG AND INNER PEEL POUCH ARE CONSIDERED STERILE.

Step 1: Remove the graft from the box packaging.
Step 2: Utilizing sterile technique, peel open the outer peel pouch from the chevron end and present the inner peel pouch to the sterile field.
Step 3: Peel open the inner peel pouch from the chevron end.
Step 4: Cut the barrier bag on one end with the aid of a pair of scissors and place the graft in a sterile basin.
Step 5: Pour sterile isotonic solution of choice into the basin until the allograft is completely immersed in solution. Antibiotics of the physician's preference may be added to the solution. After the prescribed reconstitution time, the allograft is now ready for use.
Step 6: If the allograft is to remain in solution for more than 2 hours, the graft must be stored in the refrigerator at 1 to 10°C until the time of surgery. Before placing the graft in cold storage, ensure the rim of the basin is dry and cover and seal the basin with a sterile Vi-Drape or similar adhesive drape. Double wrap the sealed basin with sterile waterproof wrappers.

If packaged in an Innermost container and two-layer peel pouch configuration: (applicable to OsteoAMP allografts)

The allograft is aseptically packaged in a plastic container, one tear pouch and one peel pouch.
THE PLASTIC CONTAINER AND INNER TEAR POUCH ARE CONSIDERED STERILE.

Step 1: Utilizing sterile technique, peel open the outer peel pouch from the chevron end and present packaged graft to the sterile field.
Step 2: Place the packaged graft into a small basin on the sterile field, locate the tear notch and tear open.
Step 3: Remove the container from the inner pouch and unseal the container.
Step 4: Transfer the graft into the same basin and pour about 5 to 10 ml of sterile solution of choice into the basin. Antibiotics of choice may be added to the solution if desired.
Step 5: Once completely reconstituted, the graft is ready for use. (It is advisable to implant the graft within 2 hours post reconstitution.)

If packaged in a vacuum sealed bottle:

Step 1: Remove the graft from the box packaging.
Step 2: Cut the tamper evident seal with the aid of a pair of scissors and remove the plastic cap.
Step 3: Disinfect the rubber stopper with a bactericidal prep pad followed by alcohol or similar disinfectant.
Step 4: Insert a 22 or 23 gauge needle into the rubber stopper in order to release the vacuum in the bottle.
Step 5: Once the vacuum is released, remove the needle from the stopper, remove the stopper with a towel clip, Kocher clamp or a similar instrument in a manner that the lip of the bottle does not become contaminated.
Step 6: Utilizing sterile technique, remove the allograft from inside the bottle with the aid of sterile forceps or similar instrument and place the allograft in a sterile basin.
Step 7: Pour sterile solution of choice into the basin until the allograft is completely immersed in solution. Antibiotics of the physician's preference may be added to the solution. After the prescribed reconstitution time, the allograft is now ready for use.
Step 8: If the allograft is to remain in solution for more than 2 hours, the graft must be stored in the refrigerator at 1 to 10°C until the time of surgery. Before placing the graft in cold storage, ensure the rim of the basin is dry and cover and seal the basin with a sterile Vi-Drape or similar adhesive drape. Double wrap the sealed basin with sterile waterproof wrappers.

TISSUE TRACKING INSTRUCTIONS

It is the responsibility of the end-user or the clinician to provide the University of Miami Tissue Bank with information pertaining to the traceability of the implanted tissue[8]. For this purpose, a postage paid *Tissue Utilization Report* (TUR) card is provided with the allograft. Once the graft is implanted, peel off the small product labels provided on the product packaging and affix on the TUR card and applicable patient records. Complete the TUR card and mail to the University of Miami Tissue Bank.

References

1. Standards for Tissue Banking, American Association of Tissue Banks, 12th Edition, Issued February 2008. **(Accredited)**
2. Code of Federal Regulations, Title 21 Part 1271 – Donor Eligibility and Good Tissue Practice (GTP) regulations for Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps), U.S. Food and Drug Administration. Final Rule November 24, 2004. **(Registered)**
3. Florida Administrative Code Chapter 59A, Regulations of the Agency for Health Care Administration of the State of Florida. 1996. **(Certificate Issued)**
4. Part 52 of Title 10 (Health) of the Official Compliance of Codes, Rules & Regulations of the State of New York, February 24, 2007. **(Licensed)**
5. Title 10 Subtitle 50 Chapter 01 of the Official Compliance Codes, State of Maryland Department of Health and Mental Hygiene, December 1999. **(Permit Issued)**
6. Chapter 4.1 & Chapter 4.2 of the California Health and Safety Code, State of California Department of Health Services, January 2011. **(Licensed)**
7. Chapter 28 of Title 16 Health and Safety Delaware Code, February 22, 2011. **(Registered)**
8. Accreditation Program. Hospital Transplant Safety, The Joint Commission on Accreditation of Healthcare Organizations, 2008. **(Licensing Not Applicable)**
9. Commission Directive 2006/17/EC of 8 February 2006. Directive 2004/23/EC, Official Journal of the European Union, February 2006. **(Pending Registration)**
10. *SOR/2007-118, Safety of Human Cells, Tissues and Organs for Transplantation Regulations of the Food and Drugs Act, Minister of Justice of Canada, June 7, 2007.* ***(Registered)***

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