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\(^3\), the European Union\(^4\), and Health Canada\(^5\). 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.

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, Hydrogen Peroxide, and Phosphate Buffer solutions (applicable to demineralized grafts) may remain in the tissue. Individuals with known sensitivities to any of these agents should not receive this allograft.

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 above.

OVER

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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. It is the responsibility of the end-user to store tissues in appropriate storage conditions prior to further distribution or transplant. 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 TRANSPLECTED (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 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 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.

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.

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 to the TUR card and applicable patient records. Complete the TUR card and mail to the University of Miami Tissue Bank, scan and e-mail to umbturs@med.miami.edu or Fax to (888) 630-4321.

References

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, April 1, 2010. (Registered)
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)
10. 80/2007-118, Safety of Human Cells, Tissues and Organs for Transplantation Regulations of the Food and Drugs Act, Minister of Justice of Canada, December 2012. (Registered)