WISHBONE MEDICAL

ALLOMate
BONE PIN SYSTEM

STERILE HUMAN ALLOGRAFT: INSTRUCTIONS FOR USE

Tissue ID Number:

Place Sticker Here

DESCRIPTION

This graft was prepared from tissue acquired from cadaveric donated human tissue. Eligibility for implantation was determined based on the result of donor screening and testing, using aseptic surgical techniques. This allograft was prepared from tissues which may have been treated with betadine, 70% isopropyl alcohol, Triton-X 100, hydrogen peroxide, hydrochloric acid, and phosphate buffer solution and may contain trace residuals of these agents. Caution should be exercised if the patient has a known sensitivity or allergy to any of these reagents. This graft is terminally sterilized via gamma irradiation.

STORAGE

Freeze-dried/lyophilized allografts can be stored refrigerated (1°C to 10°C) or at 15°C to 30°C until expiration date shown on allograft label.

INSTRUCTIONS FOR PREPARING ALLOGRAFT FOR ADMINISTRATION

It is recommended to rehydrate allografts in Lactated Ringers, normal saline, or other normal physiologic solution containing antibiotics of the surgeon's preference.

1. Open carton and remove container.
2. Using standard sterile technique, peel open pouches and hand over innermost container to sterile team member.
3. Cut open innermost packaging using sterile scissors or open the jar and remove tissue.
4. Place the allograft in a sterile basin (or equivalent) containing saline or isotonic solution of choice.
5. Addition of antibiotics of choice is optional.
6. Crushed bone (e.g. cancellous, corticocancellous, bone powder, etc.), DBM fiber, frozen and lyophilized soft tissues (e.g. fascia) should be reconstituted for approximately 60 minutes to allow for complete thawing. Weight-bearing allografts (e.g. tri-cortical wedges, segments, struts, etc.) should be reconstituted for 2-4 hours.
7. Allograft should be implanted as soon as possible after reconstitution. Tissue should be used within 6 hours of opening container if stored at ambient temperature, or within 36 hours if stored refrigerated with proper precautions to prevent contamination. Reconstitution times may vary with the type and size and intended use of the allograft.
8. Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.

TREATMENT WITH GAMMA IRRADIATION

Donor tissue is recovered using the safest recovery techniques and sterile equipment to minimize any bioburden contamination. All tissues are procured via a network of qualified and trained recovery partners, one of the most stringent screening and recovery protocols, tissue cleaning and validated sterilization processes, and a highly controlled processing environment, thus countering the risks of disease transmission at every step. Subsequently, all allografts are terminally sterilized using gamma irradiation to ensure patient safety. The effects of low dose irradiation on the biological properties of human allograft tissues are not fully understood at this time.

INDICATIONS AND USAGE

This allograft may be used in situations where an autograft is appropriate, such as in spinal fusion procedures. It should be restricted to homologous use for the repair, replacement, or reconstruction of musculoskeletal defects.

- Intended for use in one patient, on a single occasion only
- Only qualified health care professionals (e.g. physicians, dentists, podiatrists, etc.) should transplant donated human tissue
- Tissue may not be re-sterilized
- Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.
- WishBone Medical and Pinnacle Transplant Technologies (PTT) assume no responsibility for the clinical use of this allograft tissue
- Tissues may transmit infectious disease agents. Any adverse outcomes that may be attributable to the implantation of this allograft tissue must be reported to WishBone Medical as soon as possible.

DONOR SCREENING AND TESTING

Only donors from federally designated Organ Procurement Organizations (OPOs) or qualified tissue recovery partners are accepted. PTT is responsible for donor screening, tissue processing, and distribution services for our partners. Each partner is routinely audited to guarantee their recovery practices meet current FDA regulations, AATB standards and PTT's own stringent guidelines. Prior to release for transplantation, each donor is subjected to a thorough eligibility evaluation including review of the donors medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical assessment. Testing* includes, but is not limited to, the following:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
- HCV NAT: Hepatitis C Virus
- HIV NAT: Human Immunodeficiency Virus
- HBV NAT: Hepatitis B Virus
- RPR/STS or Equivalent: Syphilis

* HTLV I/II testing may have been performed, if testing was performed results were found to be negative/nonreactive.

All required communicable disease tests are negative/nonreactive. Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. Names and addresses of testing laboratories, and a listing of the documents reviewed as part of the relevant medical records are kept on file at PTT and are available to the End-User upon request through WishBone Medical, except such information that may infringe upon the confidentiality of the donor information.

Based on all the screening and testing results this donated human tissue product has been determined to be suitable for transplant by the Medical Director and Quality Assurance.

PRECAUTIONS

Because of potential violations of sterility, this allograft must not be transplanted under the following conditions:

- The container in which the product is stored is damaged compromising packaging integrity
- The tissue outer packaging is damaged or missing
- The expiration date has been exceeded
- The allograft is not labeled, or the label's information is damaged, defaced or illegible
- The allograft has not been stored according to acceptable storage conditions outlined in this Package Insert
- If any of the allograft or package elements appear to be missing, damaged or tampered with
- If the product label or identifying barcode is severely damaged, illegible or missing.
- If any of the aforementioned conditions exist or are suspected, please notify WishBone Medical immediately for resolution.

CONTRAINDICATIONS, SIDE-EFFECTS AND HAZARDS

No contraindications are known to exist. A relative contraindication would include the presence of infection in the host bed where the allograft is implanted. Limitations of allografts include slow and/or incomplete incorporation and/or resorption which may be due to the difference in histocompatibility factors between the donor and recipient. Bacterial infection at the site of implantation may occur. This complication may not be apparent for long periods of time (6-24 months) after transplantation. Transmissions of infectious disease may occur despite rigorous donor selection and testing.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Inherent uncertainties exist in medical and social histories and lab testing which may not detect known or unknown pathogens. Therefore, the following complications may occur with tissue transplantation:

- Transmission of disease of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi;
- Immune rejection of implanted HCT/P; or
- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration.

Report any adverse outcomes to WishBone Medical immediately.

HCT/P TRACKING

Per 21 CFR 1271.290(e), documentation about the tissue disposition to enable tracking from the donor to the consignee or final disposition must be maintained. Joint Commission standard QC.5.310.7 requires that "the organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities." To comply with these requirements, a Tissue Transplant Record (TTR) and preprinted labels are provided with every allograft. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using stickers) and comments regarding tissue on the TTR. Return the completed TTR to Pinnacle Transplant Technologies and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, a completed TTR with the allograft identification information and reason for discard needs to be returned to Pinnacle.

RETURN POLICY

WishBone Medical is committed to honoring the altruism of tissue donation. In accordance with this commitment, WishBone Medical may accept returned allografts for credit or exchange (less a handling fee) based on stringent criteria. The specific criteria for returning allograft tissue products ensure that the viability of the graft is not compromised.

PRODUCT COMPLAINTS

Any health care professional (e.g. customer or user of this system of products) who has experienced dissatisfaction in this product's quality, identity, durability, reliability, safety, effectiveness and/or performance, should either notify their WishBone Medical, Inc. sales representative or contact WishBone Medical, Inc. at WeCare@WishBoneMedical.com. When filing a complaint, please provide the following information:

- Nature of the complaint
- Location of the incident
- Name and address of complainant
- Device name(s) and part number(s)
- Device lot number(s)
- Device UDI (if available)
- Patient name or patient identifier
- Patient age & gender

FOR FURTHER INFORMATION

Please contact WishBone Medical, Inc. at www.WishBoneMedical.com or contact your authorized representative for further information about this product.

DISTRIBUTED BY:

WISHBONE MEDICAL

100 Capital Drive
Warsaw, IN 46962 U.S.A.
+ 1 (574) 306-4006
www.WishBoneMedical.com
WeCare@WishBoneMedical.com

PROCESSING AND DONOR ELIGIBILITY DETERMINED BY:

Pinnacle Transplant Technologies
1125 W. Pinnacle Peak Rd Building #1
Phoenix, AZ 85027
(623) 277-5400

Disclaimer: It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant and that recipient records must be maintained for the purpose of tracing tissue post-transplantation. Pinnacle Transplant Technologies will not be liable for any damages, whether direct or indirect, special, incidental or consequential resulting from improper use of this allograft. The instructions for use are specific, and Pinnacle Transplant Technologies waives all responsibility associated with mishandling, inappropriately storing and/or not taking proper precautions with the allograft tissue included with this insert.