STERILE HUMAN ALLOGRAFT: INSTRUCTIONS FOR USE

Tissue ID Number:

Place Sticker Here

DESCRIPTION

This unit of allograft is derived from DONATED HUMAN TISSUES. The tissue was prepared from a donor prepared by an accredited human tissue bank in the USA. The tissue is determined to be suitable for transplant by the tissue bank Medical Director based on the results of screening and testing. Recovery was performed using industry standard procedures in a controlled tissue processing environment designed to ensure tissue allograft bio-implant quality and safety. The tissue bank utilizes a proprietary series of disinfection soaks validated to significantly reduce bioburden prior to terminal sterilization via gamma irradiation. 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.

STORAGE

Freeze-dried/lyophilized allografts must be stored at ambient temperatures (15°C to 30°C) until expiration date shown on allograft label.

INSTRUCTIONS FOR PREPARING ALLOGRAFT FOR ADMINISTRATION

It is recommended to rehydrate allografts with the patient's blood, bone marrow or normal saline.

1. Open carton and remove container.
2. 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. Rehydrate the implant with preferred fluids until desired consistency is achieved.
5. Allograft should be implanted as soon as possible after reconstitution. Tissue should be used within 6 hours of opening.
6. Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded using hospital practices.

TREATMENT WITH GAMMA IRRADIATION

Donor tissue is recovered using the recovery techniques and sterile equipment to minimize bioburden contamination. All supplied tissues are procured via a network of qualified and trained recovery partners using stringent screening and recovery protocols, validated tissue cleaning and sterilization processes, and a controlled processing environment. Subsequently, all allografts are terminally sterilized using Gamma irradiation with a dose ≥15.8 kGy or ≥20.1 kGy 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 further processed (sterilized or re-sterilized)
- Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use
- Infinity Biologics nor the processing tissue bank assume any 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 Infinity Biologics and the tissue bank as soon as possible

DONOR SCREENING AND TESTING

The processing tissue bank only accepts donors from federally designated Organ Procurement Organizations (OPOs) or qualified tissue recovery partners. As these organizations are focused primarily on organ donation and tissue recovery, the tissue bank is responsible for donor screening, tissue processing, and distribution services for our partners. Each partner is routinely audited to assess their recovery practices meet current FDA regulations, AATB standards and the tissue bank's own processing and testing guidelines. Prior to release for transplantation, each donor is subjected to 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 must be negative/nonreactive. Communicable disease testing are 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). 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 the processing tissue bank and are available to the End-User upon request, except such information that may infringe upon the confidentiality of the donor information.

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 tissue is not within the expiration date requirements
- 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 Infinity Biologics or the processing tissue bank immediately for resolution

CONTRAINDICATIONS, SIDE-EFFECTS AND HAZARDS

No absolute contraindications are known to exist. Trace amounts of Triton X-100, isopropyl alcohol, hydrogen peroxide, hydrochloric acid, phosphate buffered saline and betadine may be present and caution should be exercised if the patient is allergic to any of these agents. 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.

Immediately report any suspected product related severe adverse events to Infinity Biologics and the processing tissue bank.

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 and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, a completed TTR must be returned.

RETURN POLICY

Infinity Biologics is committed to honoring the altruism of tissue donation. In accordance with this commitment, Infinity Biologics 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. Please refer to our Tissue Return Policy included with each allograft for more complete instructions.

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. Infinity Biologics nor the processing tissue bank will 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 both Infinity Biologics and the processing tissue bank waives all responsibility associated with mishandling, inappropriately storing and/or not taking proper precautions with the allograft tissue included with this insert.

PROCESSING AND DONOR ELIGIBILITY DETERMINED BY:

Pinnacle Transplant Technologies
1125 W. Pinnacle Peak Rd Building #2, Suite 116
Phoenix, AZ 85027
(623) 277-5400

MARKETED BY:

Infinity Biologics
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(877) 299-2772