STERILE HUMAN ALLOGRAFT: INSTRUCTIONS FOR USE

DESCRIPTION
Surgical Esthetics provides allografts derived from DONATED HUMAN TISSUES. This tissue was prepared from a donor determined to be suitable for transplant by the Pinnacle Transplant Technologies (PTT) Medical Director based on the results of screening and testing. Recovery was performed using sterile surgical procedures and Pinnacle Transplant Technologies’ controlled tissue grafts processing environment is designed to ensure tissue allograft bio-implant quality and safety. PTT utilizes a proprietary series of disinfection and sonication 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 PVP, 70% isopropyl alcohol, Triton-X 100, hydrogen peroxide, hydrochloric acid, peracetic acid and phosphate buffered saline and may contain trace residuals of these agents.

STORAGE
Freeze-dried/lyophilized allograft can be stored at ambient temperature (15-30°C or 59-86°F) until expiration date shown on allograft label. The user facility and clinician is responsible for maintaining allograft tissue in appropriate storage conditions prior to transplant.

INSTRUCTIONS FOR PREPARING ALLOGRAFT FOR ADMINISTRATION
It is recommended to rehydrate allografts in Lactated Ringers, normal saline, or other normal physiologic solution of the surgeon’s preference.

1. Open carton and remove pouch container(s).
2. If allograft is packaged in a vial:
   a. Open jar/vial and remove tissue.
   b. Place the allograft in a sterile basin (or equivalent) containing desired solution of choice. Ensure allograft is completely submerged in the solution.
   c. Proceed to step 4.
3. If allograft is packaged in pouches:
   a. Peel open outer dust cover and middle pouch container.
   b. Hand innermost pouch container to sterile team member.
   c. Cut open innermost packaging using sterile scissors and remove tissue.
   d. Place the allograft in a sterile basin (or equivalent) containing desired solution of choice.
4. Addition of antibiotics of choice is optional.
5. Sponge allografts (e.g. demineralized sponge strips/blocks, etc.) and crushed bone (e.g. cancellous, corticocancellous, bone powder, etc.) should be reconstituted for approximately 5-30 minutes. Allografts may be placed in a refrigerator for the rehydration process.
6. Allograft should be implanted as soon as possible after reconstitution.
   a. 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.
7. Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.

TREATMENT WITH GAMMA IRRADIATION
STERILE R
Donor tissue is recovered using the safest recovery techniques and sterile equipment to minimize any bioburden contamination. All PTT tissues are procured via a network of qualified and trained recovery partners, one of the most stringent screening and recovery protocols, validated tissue cleaning and 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 with a dose ≥ 15.8 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
Surgical Esthetics’ allografts may be used in situations where an autograft is appropriate, such as ridge preservation 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 sterilized or re-sterilized
- Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use
- PTT and Surgical Esthetics assumes 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 Surgical Esthetics as soon as possible.

DONOR SCREENING AND TESTING
PTT 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, PTT is responsible for donor screening, tissue processing, and distribution services for our partners. Each donor is routinely audited to ensure that 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). 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 Pinnacle and are available to the End-User upon request, 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 allograft's 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 Surgical Esthetics immediately for resolution.

CONTRAINdications, SIDE-EFFECTS AND HAZARDS
No absolute contraindications are known to exist. Trace amounts of Triton X-100, isopropyl alcohol, PVP, hydrogen peroxide, peracetic acid, hydrochloric acid and phosphate buffered saline 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.
Report any adverse outcomes to Surgical Esthetics immediately.

HCT/P TRACKING
Per 21CFR1271.230(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 Tracking Record (TTR) and preprinted labels is provided with every graft. 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 form 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 PTT.

RETURN POLICY
Surgical Esthetics (SE) is committed to honoring the altruism of tissue donation. In accordance with this commitment, SE will accept returned allografts for credit (less a handling fee). The specific criteria for returning allograft tissue products ensure that the viability of the graft is not compromised and are listed below:

1. Allograft must be returned within 6 months of the tissue expiration date.
2. Packaging must be intact and unopened.

3. Graft must have been maintained according to the specified storage conditions.
4. Responsibility for facilitating shipping arrangements must be assumed by the returning healthcare facility.
5. Returning facility must complete, sign and return an SE Tissue Return Authorization Form stating that all of the required criteria have been met. Call the SE customer service department at (214) 756-6052 for a Return Authorization Number (RAI) prior to shipment return. Credit cannot be issued if the Tissue Return Authorization Form has not been completed by the returning facility and received by SE.

LABEL AND PACKAGE SYMBOL DEFINITIONS

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>See instructions for use</td>
</tr>
<tr>
<td>R</td>
<td>For prescription use only</td>
</tr>
<tr>
<td>STERILE R</td>
<td>Sterile by Gamma Irradiation</td>
</tr>
<tr>
<td>2</td>
<td>Do not reuse; Single patient use only</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number (Tissue ID number)</td>
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<tr>
<td>LOT</td>
<td>Lot number (Donor number)</td>
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MARKETED BY:
Surgical Esthetics, LLC
19355 Business Center Drive Unit # 8
Northridge, CA 91324
(818) 701-5245

PROCESSING AND DONOR ELIGIBILITY DETERMINED BY:
Pinnacle Transplant Technologies
1125 W Pinnacle Peak Rd
Bldg. #2
Phoenix, AZ 85027
(602)-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. Surgical Esthetics and 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 Surgical Esthetics 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.