



Allograft Tissue Information and Instructions for Use

Contents

This package contains Donated Human Tissue Allografts as defined in USFDA 21 CFR Part 1271.

Description

Paragon 28, Inc.'s PRESERVE Bone Wedge System™ Grafts are aseptic, freeze dried Allografts produced by DCI Donor Services (DCIDS) Tissue Bank from donated human bone tissue. DCIDS Tissue Bank is a full service not-for-profit tissue bank accredited by AATB and registered with FDA

Donor Screening for Tissue Procurement

An appropriate blood sample from the donor is tested for relevant communicable disease tests by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 using, when available, FDA-licensed test kits. DCIDS only releases tissue for transplantation that has negative or non-reactive results for the following:

- anti-HIV-1 and anti-HIV-2
- HIV-1/HCV NAT
- Hepatitis B surface Antigen (HBsAg)
- Hepatitis B Core total antibody (anti-HBc)
- Hepatitis C antibody (anti-HCV)
- Syphilis

These test results, donor risk assessment questionnaire, physical assessment/examination and other available relevant donor records have been evaluated by DCIDS and deemed suitable for transplant by a licensed physician Medical Director.

Processing

Technical Quality Assurance standards are rigorously maintained by DCI Donor Services – Tissue Bank (DCIDS). Tissue is processed aseptically in a controlled, ultra clean environment. This tissue was processed using some or all of the following agents: Bacitracin, Polymyxin B Sulfate, Gentamycin, Allowash®, and Alcohol. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the medications and chemicals may remain. The processing method **does not** include Hydrogen Peroxide. Tissue is not released for transplantation unless the final culture results support no bacterial growth.

Contraindications

- Active or latent infection in or around the surgical implantation site
- Sensitivity or allergies to any of the processing agents listed under the processing section of this document
- Use in immune compromised patients

Warnings & Precautions

As with all allogeneic materials, it is not possible to provide an absolute guarantee that no infectious disease will be transmitted. However, this risk is greatly reduced by using processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening criteria, laboratory testing, aseptic processing and gamma irradiation of the final product.

- **Single patient, single use only.**
- **Do not sterilize or resterilize.**
- Return all packages with flaws to Paragon 28, Inc.
- Do not use if expiration date has been exceeded.
- Recommended storage conditions and the maintenance of the tissue for transplantation are the responsibility of the hospital or clinician. Do not use if tissue has not been stored according to the recommended storage instructions.
- Prior to clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the product.
- Antibiotic acceptability must be discussed with the patient to discern patient status regarding antibiotic sensitivity.

Complications and Possible Adverse Effects

Inherent uncertainty exists 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 diseases 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 Paragon 28, Inc. immediately.

Tissue Preparation/Rehydration

Prior to surgery, carefully follow the tissue preparation steps as described below. It is recommended that freeze-dried allografts be rehydrated in Lactated Ringers, Normal Saline, or other normal physiologic solution containing antibiotics of the surgeon's preference.

Non-Sterile Team Member

1. Visually inspect packaging to ensure that it is intact and that its integrity has not been compromised. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
2. Peel open outer heat sealed package and drop the inner envelope packing onto the sterile field

Sterile Team Member

3. Visually inspect the envelope to ensure that it is intact and that its integrity has not been compromised. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
4. If no damage is detected, open and place the graft into a sterile basin for reconstitution.
5. Completely submerge the graft in ambient temperature sterile rehydrating solution.
6. Rehydrate allografts for a minimum of 5 minutes.
7. Rinse the allograft thoroughly with sterile irrigant prior to transplantation.
8. The graft is ready for implantation. Do not allow graft to dry. Keep graft completely submerged in sterile solution until surgically implanted.
9. Once rehydrated, allografts must be used immediately (within 24 hours if refrigerated at 4°C) or discarded. **Do not return reconstituted unused allografts to Paragon 28, Inc.**
10. It is recommended that allograft be cultured, immediately prior to transplant.

HCT/P Tracking

Paragon 28, Inc. is required by 21 CFR 1271 to maintain documentation about the disposition of each tissue to enable tracking from the donor to the consignee or final disposition. Joint Commission standards require 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, DCIDS Tissue Bank provides an *Allograft Implant Record (AIR)* and preprinted labels 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 AIR. Return the completed form to DCIDS - Tissue Bank and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, complete the AIR with the allograft identification information and reason for discard and return to DCIDS - Tissue Bank.

Storage and Handling

It is the responsibility of the user facility and user clinician to maintain allograft tissue in appropriate storage conditions prior to transplant. All freeze-dried allografts must be maintained at ambient temperature prior to reconstitution. **DO NOT FREEZE.**

Return Policy

Paragon 28, Inc. 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. Graft must be returned within 30 days of receipt.
2. Packaging must be intact and unopened.
3. Graft must have been maintained in the appropriate environment.
4. Responsibility for facilitating shipping arrangements must be assumed by the returning healthcare facility.
5. Returning facility must complete, sign and return a Paragon 28, Inc. Tissue Return Authorization Form stating that all of the required criteria have been met. Please contact Paragon 28, Inc. at (888) 728-1888 for a Return Authorization Number (RA#) 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 Paragon 28, Inc.

Disclaimer

Paragon 28, Inc. makes no claims concerning the biologic or biomechanical properties of allograft tissue. All tissue has been collected, processed, stored and distributed according to nationally recognized standards and in compliance with the U.S. Food and Drug Administration. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. Adverse outcomes potentially attributable to the tissue must be reported immediately to Paragon 28, Inc. using a “Report of complaint/complication” form. Please contact the company for the form if needed.

Tissue Processed by:

DCI Donor Services - Tissue Bank

1714 Hayes Street
Nashville, TN 37203
(800) 216-0319

Website: <http://tissuebank.dcids.org>

Tissue Distributed By:

Paragon 28, Inc.

4B Inverness Court E
Suite 280
Englewood, CO 80112
Ph: (888) 728 1888

Website: www.paragon28.com

CAUTION: Federal Law (USA) restricts this material for use by a licensed physician only.