Package Insert

Contents

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

Description

ALLOCYTE™ Advanced Cellular Bone Matrix is a human tissue allograft consisting of cryopreserved cancellous bone combined with cortical fibers.

Donor Screening

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 and 42 CFR part 493 using, when available, FDA-licensed test kits. Origin Biologics only releases tissue for transplantation that has negative or non-reactive results for the following:

- anti-HIV-1 and anti-HIV-2
- HIV-1/HBV/HCV NAT
- Hepatitis B surface Antigen (HBsAg)
- Hepatitis B Core total antibody (anti-HBc)
- Hepatitis C antibody (anti-HCV)
- Syphilis
- Cytomegalovirus (CMV)
- HTLV I/II

Additional tests for other communicable diseases, such as West Nile Virus, T. Cruzi, and Epstein Barr Virus may have been performed. The results of all additional communicable disease tests have been evaluated by the Medical Director and have been found acceptable according to regulations, standards and Origin Biologics policies and procedures. These test results, donor risk assessment questionnaire, physical assessment/ examination and other available relevant donor records have been evaluated by Origin Biologics and deemed eligible for transplant by a licensed physician Medical Director.

Processing

Technical Quality Assurance standards are rigorously maintained by Origin Biologics. Processing is performed in a controlled, ISO Class 5 environment. All tissue is recovered and processed using aseptic techniques. No aseptic tissue is released for transplantation unless the final culture results support no bacterial growth.

HCT/P Tracking

Origin Biologics 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. To comply with these requirements, an Allograft Implant Record (AIR) and preprinted labels are included with every graft. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using preprinted labels) and comments regarding tissue on the AIR. Return the completed form to Origin Biologics per the printed instructions on the AIR and retain a copy in the patient medical record. If the tissue has been discarded and not subsequently implanted for any reason, the AIR must be completed with the reason for discard identified.

Contraindications

- Do not use if active or latent infection is present in or around the surgical implantation site.
- Do not use if patient has sensitivity or allergies to any of the processing agents listed below.
- Do not use in immune compromised patients.

Warnings and Precautions

The following precautions must be taken with this allograft:

- Single patient, single use only.
- Do not sterilize or re-sterilize.
- Do not use if packaging has been compromised. Return all allografts with compromised packaging to Origin Biologics.
- Do not use if the expiration date has been exceeded.
- Use of this tissue is limited to specific health professionals (e.g. physicians, dentists and/or podiatrists).
- Do not use if the tissue has not been stored in accordance with the storage instructions specified in this insert.
- Tissue is stored with Cryopreservation solution (DMSO-free) at a concentration of 35%-40% of graft volume.
- This tissue was processed using some or all of the following agents: Amphotericin B, Vancomycin, Gentamicin, Dulbecco's Modified Eagle's Medium (DMEM), Citric Acid, Sodium Citrate, Glucose, Hydrochloric Acid, Phosphate Buffered Saline (PBS), Sodium Deoxycholate, Isopropyl Alcohol, Hydrogen Peroxide and trace amounts may remain. Use of antibiotics should be discussed with the patient to discern patient status regarding antibiotic sensitivity.

Inherent uncertainty exists in donor screening and laboratory testing which may not detect known or unknown pathogens.

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 the implanted HCT/P; or
- Loss of function and/or integrity of the implanted HCT/P due to resorption, fragmentation, and/or disintegration.

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 and validated processing methods. **Adverse outcomes potentially attributed to the tissue must be reported to Origin Biologics or Sanara MedTech Inc. immediately**.

Return Policy

Claims for order discrepancies, shipping errors, damaged allografts or packaging must be reported to Sanara MedTech Inc. within ten (10) business days to be eligible for credit. Returns will not be accepted.

Transportation and Storage

ALLOCYTE™ Advanced Cellular Bone Matrix is shipped frozen and must be stored in its original packaging at or below -70°C (-94°F) until ready for use. The allograft should be implanted or transferred to a -70°C freezer the same day. It is the responsibility of the end user to document the maintenance of the HCT/P at these storage conditions.

Tissue Preparation

Prior to surgery, carefully follow the appropriate preparation methods specified below. Use of antibiotics must be discussed with the surgeon to discern patient status regarding antibiotic sensitivity. It is the responsibility of the Distributor and/or End-User to maintain tissue at the appropriate storage conditions described above.

1. Using sterile technique, peel open the outer foil pouch and transfer the inner pouch into the sterile field.
2. Open the inner pouch and transfer the graft into a basin containing room temperature thawing solution such as sterile water or sterile saline.
3. Warning: Do not use water/saline at a temperature greater than 39°C (102.2°F).
4. Allow graft to thaw (approximately 10 minutes).
5. Once thawed, the tissue is ready for use and should be implanted within 5 hours.
6. Note: It is not necessary to decant and discard excess preservation solution. The graft can be extruded and used as supplied in the syringe.

Note: Once the inner pouch containing ALLOCYTE™ Advanced Cellular Bone Matrix has been opened, the allograft must be transplanted during that surgical procedure or discarded.

Disclaimer

Origin Biologics and Sanara MedTech Inc. make 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 applicable U.S. Food and Drug Administration requirements. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. **Adverse outcomes potentially attributed to the tissue must be reported to Origin Biologics or Sanara MedTech Inc. immediately.**

Donor Assessment, Tissue Processed, Released for Distribution and Distributed by:
Origin Biologics – Tissue Bank
6635 S. Eastern Avenue, Suite 100
Las Vegas, NV 89119 USA
702-790-7015 (within US)
www.originbio.com

Distributed by:
Sanara MedTech Inc.
1200 Summit Avenue
Suite 414
Fort Worth, Texas 76102
800-205-7719

MKT.06.02 Rev. 211118