CoreLink

Allograft Tissue Information and Preparation Package Insert

Contents

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

Description

ReStrux™ is a human tissue allograft consisting of cryopreserved cancellous bone combined with cortical fibers that have undergone a demineralization process.

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

Processing

Technical Quality Assurance standards are rigorously maintained by DCI Donor Services. Processing is performed in a controlled, ultra-clean 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

DCIDS 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 Tracing Record (ATR) 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 ATR. Return the completed form to DCIDS per the printed instructions on the ATR and retain a copy in the patient medical record. If the tissue has been discarded and not subsequently implanted for any reason, the ATR 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 DCIDS.
- 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 36%-45% 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), Bacitracin, Polymyxin B Sulfate, Brij®, Nonoxynol-9, NP-40, Isopropyl Alcohol and/or Hydrogen Peroxide. Although the tissue was rinsed with sterile water or sterile saline throughout the processing steps, 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 DCI Donor Services or CoreLink, LLC immediately.**

Return Policy

Returns of ReStrux are not accepted without prior authorization. If the product was damaged in shipment KEEP THE ORIGINAL SHIPPING CARTON and immediately call Customer Service at (888) 349-7808.

Transportation and Storage

ReStrux is shipped frozen and must be stored in its original packaging at or below -70°C (-94°F) until ready for use. The allograft must be implanted or transferred to a -70°C freezer within 12 hours of receipt. 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 (See Warnings and Precautions above). It is the responsibility of any agent of CoreLink and/or End-User to maintain tissue at the appropriate storage conditions described above.

1. Using sterile technique, peel open the outer 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. Do not remove the graft from the delivery syringe before thawing.
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 must be implanted within 4 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 ReStrux has been opened, the allograft must be transplanted during that surgical procedure or discarded.

Disclaimer

DCIDS and CoreLink, LLC 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 DCI Donor Services or CoreLink, LLC immediately.**

Donor Assessment, Tissue Processing, Release for Distribution, and Distribution by:
DCI Donor Services – Tissue Bank
566 Mainstream Dr., Suite 300
Nashville, TN 37228
800.216.0319
615.327.2381 Fax
Tissuebank.dcids.org

Available Through:
CoreLink, LLC
2072 Fenton Logistics Park
St. Louis, MO 63026
(888) 349-7808
CoreLinkSurgical.com

Symbols Glossary

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this product to sale by or on the order of a licensed practitioner	N/A
	Upper limit of temperature - Indicates the upper limit of temperature to which the product can be safely exposed	5.3.6
	Use-by-Date – Indicates the date after which the product is not to be used	5.1.4
	Lot Number – Indicates the manufacturer's batch code so that the batch or lot can be identified	5.1.5
	Reference Number – Indicates manufacturer's catalogue number so that the product can be identified	5.1.6
	Serial Number - Indicates the manufacturer's serial number so that a specific product can be identified	5.1.7
	Do not re-use - Indicates a product that is intended for one use, or for use on a single patient during a single procedure	5.4.2
	Consult instructions for use - Indicates the need for the user to consult the instructions for use	5.4.3