CoreLink

Musculoskeletal Tissue Allograft Package Insert and Tissue Tracking Information

In accordance with FDA Article 21 CFR Part 1271, this package contains donated human cells, tissues, and cellular and tissue-based products (HCT/Ps).

This human tissue allograft was processed and packaged by Surgenex®. All tissue was recovered, processed, stored, and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB), the FDA requirements for Human Cellular and Tissue Based Products (HCT/Ps 21 CFR Part 1271), and applicable State regulations. Surgenex® has determined the Donor to be eligible, based on the results of screening and testing. Screening includes a review of medical and social history, available hospital records, infectious disease testing, autopsy reports (if performed), and physical examination of the Donor, at the time of recovery. The Donor has been tested using FDA licensed, approved, or cleared donor screening test kits and was found negative or non-reactive for:

- Human Immunodeficiency Virus Types 1 and 2 Antibody (anti-HIV-1/anti-HIV-2)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody - Total (anti-HBc)
- Hepatitis C Virus Antibody (anti-HCV)
- Human Immunodeficiency Virus 1, Hepatitis B Virus and Hepatitis C Virus Nucleic Acid Test(s) (HIV 1/HBV NAT/HCV NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay

Additional tests, including but not limited to HTLV I/II, CMV or West Nile Virus, may have been performed and, if performed, were found to be acceptable for transplantation. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing in accordance with the 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).

THIS ALLOGRAFT IS SUPPLIED STERILE

This tissue allograft has been sterilized, via Gamma irradiation, to a SAL of 10^{-6} (Sterility Assurance Level). This allograft must not be sterilized or re-sterilized by your facility.

STORAGE

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant. All freeze-dried allografts must be maintained at ambient temperature, prior to reconstitution. DO NOT FREEZE. Freeze-dried allografts are provided in an inner Tyvek pouch with an outer foil pouch.

Note: Freeze Dried Allografts must be rehydrated according to the Tissue Preparation instructions listed below. Failure to rehydrate accordingly may impact the graft strength and could potentially result in graft failure.

TISSUE PREPARATION

BEFORE USE – Examine Allograft Packaging – Do Not Use This Allograft If:

1. Any of the package elements appear to be missing, tampered with or damaged. Return all allografts with compromised packaging to CoreLink.
2. The product label or identifying bar code is severely damaged, illegible, or missing.
3. The expiration date shown on the package label has been exceeded.
4. If the tissue has not been stored in accordance with the storage instructions specified in this insert.

Prior to surgery, carefully follow the appropriate preparation methods specified below. The appropriate preparation method is dependent on the tissue type and packaging method described below. See product label for method in which tissue is supplied. It is recommended that all freeze-dried allografts be rehydrated in Lactated Ringers, Normal Saline, physiologic fluid, or other normal physiologic solution containing antibiotics of the surgeon's preference. Antibiotic acceptability must be discussed with the surgeon to discern patient status regarding antibiotic sensitivity.

DBM Fiber Strips in Hydration Pouch

1. Using sterile technique, peel open foil pouch and transfer the inner pouch into the sterile field.
2. Open the inner pouch and remove the hydration pouch.
3. Using the Luer-Lock port, hydrate the graft for 1-10 minutes using surgeon's fluid of choice with enough fluid to completely cover the allograft.

Fiber Strip Size	Recommended Hydration Volume
5 cc	5 cc
10 cc	10 cc
20 cc	20 cc

4. Gently invert and rotate the pouch to ensure complete hydration of the Fiber Strip.
5. The product maintains maximal cohesion when hydrated with blood, BMA, or PRP.

The decision to rehydrate freeze-dried bone should be based upon the surgeon's preference. Inadequate rehydration may result in graft breakage or fracture. The bone tissue may be placed into a refrigerator for the rehydration process. Once rehydrated, allografts must be used immediately (within 24 hours if refrigerated at 4°C) or discarded. Rehydrated allografts may not be returned.

WARNINGS AND PRECAUTIONS

- This allograft is intended for use in one patient, on a single occasion only.
- This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.
- Allografts are processed using some or all of the following agents: povidone iodine, physiological buffers, alcohols and saline solutions. Traces of these reagents may remain on the tissue allografts.

Although this tissue has been tested and screened for relevant communicable diseases and disease agents, and processed under aseptic conditions, application and use of any allograft tissue may potentially have negative outcomes. Occurrence of complications at the affected site may transpire post-treatment, without early warning signs. These include, but are not limited to: 1) transmission of communicable diseases; 2) transmission of infectious disease agents; 3) immune rejection of, and/or allergic reaction to the HCT/P; and 4) loss of function and/or integrity of the implanted HCT/P due to resorption, fragmentation, and/or disintegration. Any adverse outcomes potentially attributable to the HCT/P must be reported promptly to CoreLink, LLC

Caution should be taken when administering this product to immunocompromised individuals, such as patients suffering from HIV or other highly immunocompromised conditions. Although Surgenex, LLC has taken great measures to ensure the safety of our allograft products, current technologies cannot preclude the transmission of certain diseases known or unknown. Therefore, Surgenex, LLC can make no claims concerning the biological properties and safety of allograft tissue.

CoreLink, LLC and its affiliates furnish this allograft product without any expressed or implied warranties. All statements or descriptions are informational only and are not to be implied as a warranty of the allograft product. CoreLink, LLC and its affiliates make no guarantee regarding the biological characteristics of this product. The end-user shall be held responsible for determining the appropriate application and usage of this product.

Return Policy

CoreLink, LLC is committed to customer satisfaction and will gladly handle your return within 30 days of purchase. If you are not satisfied with your order, simply return it to us by following these directions:

- Please call Returns (888) 349-7808 to receive a return authorization (RGA) number. Returns will not be accepted without this number.
- All returns under an RGA require an attestation that materials have been properly stored and handled while in the returning party's possession.
- Products must be in salable condition; Product that has been opened, used, written on, or otherwise tampered with is not considered to be in salable condition. Product must be in its original purchase form.

Please note the following items are non-returnable:

- Refrigerated Items and Items specified as "Non-Returnable" on Packing Slips/Invoices
- Returns over 30 days may be subject to a 30% restocking fee.

If your merchandise was damaged in shipment:

- Please keep the original shipping carton and call Customer Service at (888) 349-7808.
- All packages returned Freight Collect or COD will not be accepted.

TISSUE TRACKING

The Joint Commission and FDA requires patient records to be properly maintained by storing the allograft ID number (LOT NUMBER) for purposes of tracking the allograft from the donor to the recipient. **Please go to our website, www.surgenex.com/allograftrecords and register by using the LOT NUMBER located on the product label.**

Distributed By:

CoreLink

2072 Fenton Logistics Park
St. Louis, MO 63026
(888) 349-7808
CoreLinkSurgical.com

Donor Eligibility Determination Made By:

SURGENEX
Pioneering the Future Today

15444 N. 76th St., #C110
Scottsdale, AZ 85260
(877) 880-1862
www.surgenex.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
	Temperature Limit - Indicates the temperature limits to which the product can be safely exposed	5.3.7
	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
	Sterilized using irradiation - Indicates a product that has been sterilized using irradiation	5.2.4
	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