CoreLink

Product Instructions and Information Guide for CoreLink Amnion Patch Allografts

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).

STORAGE

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. This allograft tissue may be stored at ambient temperature, until the expiration date, indicated on the product label.

THIS ALLOGRAFT IS SUPPLIED STERILE

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

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.
- Concentrated Sodium Chloride is used in the processing of this allograft. Trace amounts of Sodium Chloride may remain on this allograft.

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; and 3) immune rejection of, and/or allergic reaction to the HCT/P. 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.

WARNINGS AND PRECAUTIONS (continued)

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.

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.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed.

If any of the above conditions exist or are suspected, this allograft must **NOT** be used.

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POINT OF USE

Open the outer Tyvek pouch by pulling open at the chevron seal and introduce the inner, foil pouch into a pre-arranged sterile field, if applicable. Open the foil pouch, in the same manner, by pulling open at the chevron seal. For best results and easiest method of handling, grasp the allograft with forceps and remove from the pouch. Place the graft on the area of intended application and re-hydrate in-situ with sterile water or 0.9% Saline. Secure the allograft in place using a secondary dressing.

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/surgraftrecords and register by using the LOT NUMBER located on the product label.**

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.

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.

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