STRAVIX PL

Lyopreserved Umbilical Tissue

DESCRIPTION

StravixPL lyopreserved umbilical tissue is composed of the umbilical amnion. StravixPL HCT/P is white to buff colored and its thickness may vary. The tissue becomes thicker upon rehydration. StravixPL is a Human Cells, Tissues, and Cellular Tissue Based Product (HCT/P) as defined in 21 CFR part 1271 and Section 361 of the Public Health Service Act.

StravixPL is processed from human umbilical tissue that has been generously donated by healthy mothers who have undergone full term pregnancies and delivered healthy infants. StravixPL allografts are processed aseptically in a controlled clean room environment, following rigorous quality assurance standards, and then stored and distributed for use in accordance with the regulations in 21 CFR 1271 and the standards of the American Association of Tissue Banks (AATB).

INDICATIONS FOR USE

StravixPL may be used to repair acute and chronic wounds, including but not limited to diabetic foot ulcers, venous leg ulcers, pressure ulcers, dehisced surgical wounds, burns, acute surgical wounds, Pyoderma Gangrenosum, and Epidermolysis Bulosa. The product is limited to homologous use as a cover/wrap/barrier. StravixPL may be used in wounds encompassing both upper extremity and lower extremity acute and chronic wounds. StravixPL naturally conforms to complex anatomies and may be used over exposed bone, nerves, tendon, joint capsule, muscle, hardware, and surgical mesh.

Limitations of Use:

- Intended for use in one patient, on a single occasion only.
- The tissue is intended for use by qualified healthcare specialists such as physicians, podiatrists, or other appropriate healthcare professionals.

DOSAGE

The quantity and size of product used will vary based upon the area intended to be covered or wrapped and physician recommendation.

DONOR ELIGIBILITY – SCREENING AND TESTING

All donors have been screened and tissues recovered, processed, stored, tested, and distributed in accordance with current U.S. Federal Regulations as disseminated in 21 CFR 1271, current AATB standards, and state/local regulations as required.

StravixPL was deemed suitable for transplantation. The Medical Director or physician designee has determined that the donor of the tissue contained in this product is eligible to donate tissue for transplantation based on meeting the following criteria: (1) The results of donor screening indicated that the donor was free from risk factors for, and clinical evidence of, infection due to relevant communicable disease agents and diseases, and is neither a xenotransplantation recipient nor a close contact of a xenotransplantation recipient, and (2) the results of donor testing by the following methodologies are negative or nonreactive:

Human Immunodeficiency Virus Type 1 Antibody (HIV)
Human Immunodeficiency Virus Type 2 Antibody (HIV)
Hepatitis C Virus Antibody (HCV)
Hepatitis B Surface Antigen (HBV)
Hepatitis B Core Antibody (HBV)
Syphilis Rapid Plasma Reagin (RPR) or Treponemal Specific Assay
Human T-Cell Lymphotropic Virus Type I Antibody (HTLV)
Human T-Cell Lymphotropic Virus Type II Antibody (HTLV)
HIV/HCV/HBV Nucleic Acid Test (NAT)
West Nile Virus Nucleic Acid Test (NAT)

This testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services and registered with the U.S. Food and Drug Administration (FDA) as an HCT/P testing facility. Test methods that are FDA-licensed, approved or cleared for donor screening are used as available. The records of this testing are maintained at Smith+Nephew at the address on this document.

QUALITY CONTROL TESTING

1. Asepsis – Representative product from each lot undergoes destructive microbiological verification testing per USP <71> *Sterility Tests*. The results must show "No Growth" after 14 days incubation in growth promoting media.
2. Representative product from each lot undergoes residual moisture content analysis per USP <921> *Water Determination*. The results must demonstrate less than or equal to 10% moisture from each lot.

CONTRAINDICATIONS

There are no known contraindications for this product.

WARNINGS AND PRECAUTIONS

1. Intended for use in one patient, on a single occasion only.
2. Do not use if package integrity has been compromised. Once the user breaks the seal on the foil pouch, the tissue grafts must be transplanted or discarded.
3. Once the pouch is opened, rehydrate the product.
4. The tissue may not be sterilized or re-sterilized.
5. The tissue is intended for use by qualified healthcare specialists such as physicians, podiatrists, or other appropriate healthcare professionals.
6. The same medical/surgical conditions or complications that apply to any medical/surgical procedure may occur during or following application.
7. The healthcare professional is responsible for informing the patient of the risks associated with his/her treatment and the possibility of complications or adverse reactions.
8. The tissue is processed in controlled environments using methods designated to prevent contamination and cross-contamination of the product. Caution should be exercised for patients with known sensitivities to the following reagents used for processing, disinfection, and storage and may remain on the product:
   - ***Lyopreservation Solution***: 18.9% w/v Trehalose in Dulbecco's Phosphate Buffered Saline
   - ***Disinfection Solution*****:** 0.5% v/v Gentamicin Sulfate, 0.1% v/v Vancomycin reconstituted in Water for Injection (WFI), 1% v/v Amphotericin B, 98.4% Dulbecco's Modified Eagle's Medium (DMEM)
   - ***Processing Solution:*** DMEM, Dulbecco's Phosphate Buffered Saline (dPBS), 11% Anticoagulant Citrate Dextrose Solution in Saline, Formula A (ACD-A), 1.7% w/v Trehalose in Dulbecco's Phosphate Buffered Saline
9. Although the tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents or diseases of known or unknown etiology including, but not limited to, viruses, bacteria, and fungi (e.g. HIV or Zika virus).
10. Other complications of tissue transplantation may occur, such as immune rejection of implanted HCT/P or loss of function and/or integrity.

Please promptly report adverse outcomes to Smith+Nephew at the address on page 2 of this document.

(continued on page 2)

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TRACEABILITY

It is the responsibility of the end-user to maintain recipient records for the purpose of tracking tissue post-implantation. Please record the distinct HCT/P identification code in your records and in the patient's files. As a courtesy to the end-user clinician or facility, a Tissue Tracking Form is enclosed to help facilitate proper tracking of this tissue; when completed and returned, this form enables Smith+Nephew the ability to maintain records for the purpose of tracing the tissue post-transplant. Please complete the enclosed Tissue Tracking Form and fax to 443.378.7163 according to 21 CFR 1271.290(b) and Joint Commission Standards TS.03.02.01 and EP 7.

COMPLAINTS, ADVERSE EVENTS, AND RETURNS

To report a complaint or adverse event, please contact your sales representative, authorized distributor, or Smith+Nephew Customer Service at 888.674.9551. Adverse outcomes potentially attributed to the tissue must be promptly reported to Smith+Nephew.

Please contact your local sales representative, authorized distributor, or Smith+Nephew Customer Service for information on returns.

HOW SUPPLIED

StravixPL is supplied at Room Temperature in sheet form and packaged within a heat-sealed pouch in a cardboard box. This packaging configuration allows for the introduction of the HCT/P into the sterile field. One reimbursable unit is 1cm^2.

STORAGE CONDITIONS

The intermediary, end-user and/or clinician or facility is responsible for storing StravixPL under appropriate conditions prior to further distribution or application. StravixPL must be stored as listed in the table below.

Preservation Method	Lyopreservation
Storage Conditions	Room Temperature
Special Conditions	Single Use Do Not Freeze Do Not Refrigerate Do Not X-RAY Do Not Irradiate/Sterilize Any unused product must be discarded in biohazard waste.

EXPIRATION DATING

Shelf Life	Refer to the expiry on the labeled package.

INSTRUCTIONS FOR USE

StravixPL can be applied in an office, hospital outpatient setting, or hospital inpatient setting.

APPLICATION PROTOCOL

Prior to application, follow the preparation steps below.

1. The HCT/P is aseptically packaged in a sterile pouch in a larger foil-backed pouch. The inside of the foil-backed pouch and the inner pouch containing the product are sterile. The outside of the foil-backed pouch is not sterile.
2. Create a procedure field.
3. Fill a basin with sterile saline.
4. Grasp the chevron end of the pouch and pull the layers apart, taking care not to touch the inner pouch.
5. Remove the inner pouch.
6. Open the inner pouch and remove the mesh containing the product unit.

For application of the product, follow the steps below.

7. Remove the product from the bottom mesh and top mesh and place into saline. Ensure the tissue is completely immersed.

   Please note if the tissue is adhered to the mesh, then the tissue and mesh may be placed into the saline and allow to rehydrate. Tissue should separate from mesh once rehydrated.
8. Rehydrate the tissue until flexible (i.e. bendable).
9. Apply the unit directly to the site and wrap or suture as required.

StravixPL does not require fixation (suturing, etc.) but these methods may be used by the physician or the appropriate healthcare provider at their discretion.

For external wounds, cover the applied graft in the wound with a non-adherent dressing followed by saline moistened gauze to fill but not pack the wound, or used another dressing as appropriate for the wound type.

REAPPLICATION PROTOCOL

StravixPL may be reapplied weekly at the discretion of the responsible physician for the duration of the treatment of the patient's wound.

FDA Registration Number 3006638648
Pending patent application

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is now part of
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