

## **SurGraft FT Amniotic Tissue Allograft**

### *DONATED HUMAN TISSUE*

**SurGraft FT** is a human allograft tissue that is regulated as a human cells, tissues, and cellular and tissue-based product (HCT/P) as defined by 21 CFR Part 1271. **SurGraft FT** received written notification by the FDA's Tissue Reference Group confirming SurGraft FT meets the criteria for regulation solely under Section 361 of the PHS Act as defined in 21 CFR Part 1271.

SurGraft FT are sterile, single use, dehydrated resorbable allografts derived from donated human placental birth tissue. Allografts are processed using aseptic techniques and terminally sterilized by Electron Beam.

**SurGraft FT Membrane** is a dual layer amniotic-chorionic membrane.

### **PRODUCT USE**

SurGraft FT grafts are in sheet form. SurGraft FT grafts are intended for use as a Human Cell, Tissue, and Cellular and Tissue- Based Product (HCT/P) for repair, reconstruction, replacement and/or supplementation by providing tissue in the form of scaffolding in partial and full-thickness acute and chronic wounds. The SurGraft FT graft is intended to remain on the recipient and is absorbed into the wound bed. The graft is anchored based on the physician's choice of fixation including but not limited to Steri-Strips, surgical glue, staples, or sutures in surgical procedures when medically necessary.

### **SIZE AND STORAGE**

SurGraft FT is available in a wide range of sizes. SurGraft FT must be stored in ambient temperature at 15-30°C (59-86°F) prior to patient application. Do not freeze. May be stored up to 5 years. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End- User clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use.

### **CONTRAINDICATIONS**

Allografts including SurGraft FT should not be used on areas with active infection.

### **INSTRUCTIONS FOR IMPLANTATION**

#### **Wound Bed Preparation**

- Prepare the wound bed by using standard methods to ensure it is free of exudate and devitalized tissue. An initial excision or debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- Wait for any bleeding to stop before applying SurGraft FT grafts.
- Gently cleanse the wound surface with wound cleanser or normal saline; leave the ECM gel intact.

#### **Selection and Preparation of SurGraft FT grafts**

- Measure the wound and select the appropriate size sheet of dry SurGraft FT grafts. If necessary, the product may be additionally fenestrated or meshed with a scalpel.
- Cut the sheet to a size and shape that will cover the entire wound surface and will extend slightly beyond the wound margins.

#### **Application of SurGraft FT Allografts**

- For ease of handling, apply SurGraft FT grafts by placing it in a dry state over the wound.

- Position the dry SurGraft FT grafts to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. If multiple sheets are necessary to cover the wound, slightly overlap the edges of the sheets.
- As required, securely anchor SurGraft FT grafts with the physician's choice of fixation including but not limited to Steri-Strips, surgical glue, staples, or sutures in surgical procedures when medically necessary.
- Thoroughly rehydrate SurGraft FT grafts by applying sterile saline.
- To protect SurGraft FT grafts from adhering to the secondary dressing, apply an appropriate non-adherent primary wound dressing over SurGraft FT grafts.
- Apply an appropriate secondary dressing (multi-layer compression bandage system, total contact cast, NPWT, or other appropriate dressing) that will manage the wound exudate, keep the SurGraft FT grafts moist, and keep all layers securely in place.

### **Dressing Changes**

- To prevent damage to the newly incorporating SurGraft FT graft, only change the primary dressing as necessary, typically "one to two times" every seven (7) days.
- Change the secondary dressing as appropriate. Take care to avoid dislodging the SurGraft FT grafts when the secondary dressing is changed.

### **Wound Assessment and Wound Bed Preparation**

- Change all dressings every seven (7) days, or as necessary.

NOTE: If a gel forms on the wound surface, do not attempt to forcibly remove it. Successful absorption of SurGraft FT grafts may form a caramel-colored or off-white gel. Do not remove this gel by debridement. This caramelization contains extracellular matrix (ECM), which continues to replace deficient and missing ECM in the wound.

- As healing occurs, sections of SurGraft FT grafts may gradually peel. Carefully remove any remaining loose products around the edge as needed.
- Gently cleanse the wound surface with wound cleanser or normal saline; leave the ECM gel intact.
- Carefully reassess the wound and record healing progression such as wound dimensions, wound depth, wound type, and other relevant information.

### **Reapplication of SurGraft FT grafts and Dressing Changes**

- Change secondary dressing as needed (see "Dressing Changes").
- If the wound is free of infection and necrosis but not fully epithelialized, reapply newly prepared SurGraft FT grafts over previously absorbed application (see "Application of SurGraft FT Allograft").
- Reapply SurGraft FT grafts every seven (7) days or as needed by repeating previous application steps.

### **DONOR SCREENING AND TESTING**

Prior to processing, the donor's medical and social history were screened for conditions and disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures at Surgenex, LLC. All policies and procedures for donor screening, serologic and microbiologic testing meet current Standards established by the Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). Each donor is screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing have been reviewed by the Medical Director (or licensed physician designee) of Surgenex, LLC and the donors have been deemed eligible. Communicable disease testing is performed by an FDA- registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests have been found to be nonreactive or negative:

#### **Human Immunodeficiency Virus (HIV)**

- HIV-1/2 Antibodies (HIV1/2-Ab)
- Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)

#### Hepatitis B Virus (HBV)

- HBV Surface Antigen (HBsAg)
- HBV Core Antibody (IgG & IgM) (HBcAb) Nucleic Acid Test for HBV DNA (HBV NAT)

#### Hepatitis C Virus (HCV)

- HCV Antibody (HCVAb)
- Nucleic Acid Test for HCV RNA (HCV NAT)

#### Human T Cell Lymphotropic Virus I/II

- HTLV-I/II (Antibody HTLV-I/II-Ab)

#### Syphilis

- Rapid Plasma Reagin (RPR) Screen
- T. Pallidum IgG

#### West Nile Virus (WNV)

- Nucleic Acid Test for WNV RNA (WNV NAT)

### **PROCESSING AND STERILITY**

The donors of SurGraft FT are screened and tested for relevant communicable diseases and disease agents, including COVID-19, in compliance with the FDA regulations, relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). SurGraft FT is processed using aseptic techniques and microbiologically tested. The allograft has been terminally sterilized by electron beam radiation technology in accordance with ANSI/AAMI/ISO 11137. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

**DO NOT FREEZE** the allograft by any method.

**FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY**

**DO NOT RE-STERILIZE** the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide, or other chemical sterilant may render the allograft unfit for use.

### **WARNINGS AND PRECAUTIONS**

SurGraft FT is processed and packaged using aseptic techniques and sterilized. SurGraft FT must not be transplanted under the following conditions:

- If mishandling caused damage or contamination
- If the allograft is past its expiration date
- If any of the allograft elements, packaging, labels and/or barcodes are missing, damaged, illegible, or defaced.
- If the Amniotic Membrane has not been stored according to specifications set forth in this insert

Notify Legacy Medical Consultants immediately at (817) 961-1288 if any of these conditions exist or are suspected.

### **ADVERSE EVENTS**

Health professionals should discuss possible adverse reactions prior to product use. General risks and complications arising from applications of allografts may include but are not limited to infection, bleeding, swelling, redness, and injury to nerves and other soft tissue. Complications may occur with allograft use, including but not limited to:

- Transmission of disease of unknown etiology
- Transmission of infectious agents including but not limited to HIV, hepatitis, syphilis, or microbial contaminants.
- Graft-versus-host immune rejection or other allergic reactions

Adverse outcomes potentially attributable to SurGraft FT or other complaints must be promptly reported to Legacy Medical Consultants at (817) 961-1288.

### **HCT/P TRACKING**

FDA 21 CFR 1271.290, Regulation of Human Cells, Tissue, and

Cellular and Tissue-Based Products (HCT/Ps) requires that documentation regarding tissue disposition enabling tracking from donor to the consignee and/or final disposition be maintained. Joint Commission standard QC.55.310.7 requires that the organization that receives tissue provides a system that fully complies with the completion of tracking tissue usage via Tissue Tracking/Transplant Record (TTR) or provides a web-based program for traceability of the allograft used.

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide the information pertaining to the traceability of the allograft used. Please turn in the TTR card information as directed in the shipment or visit [www.surgenex.com/surgraftrecords](http://www.surgenex.com/surgraftrecords) and register the LOT NUMBER located on the product label.

### **RETURNED GOODS POLICY**

Legacy Medical Consultants may accept return of SurGraft FT allografts for credit or exchange if incorrect product was shipped or product was received in a damaged state. Legacy Medical Consultants reserves the right to reject a return if any of the condition are not met:

1. For damaged items and incorrect shipments, Legacy Medical Consultants may replace the product with the appropriate product or issue a credit.
2. A Return Material Authorization (RMA) number must be obtained from Legacy Medical Consultants no later than 24 hours from receipt for damaged product or incorrect shipments.
3. Original product packaging must be intact and unopened.
4. Responsibility for facilitating shipping arrangements must be assumed by the returning facility unless the allograft is damaged or defective. Returning facility must complete, sign, and return the RMA form stating that all required criteria have been met.
5. Credit cannot be issued if the RMA form has not been completed by the returning facility and received by Legacy Medical Consultants. Please contact Legacy Medical Consultants immediately at (817) 961-1288 if you experience a problem with our product.

#### **Distributed By:**

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