CYGNUS® DUAL

DONATED HUMAN TISSUE

RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED HEALTH CARE PROFESSIONAL (physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant). NOT INTENDED FOR VETERINARY USE.

80-325 Rev. 04

DESCRIPTION

CYGNUS® Dual is a terminally sterilized, dehydrated amniotic membrane graft. The epithelial basement membrane and intact extracellular matrix scaffold of this tissue graft provide a protective covering from the surrounding environment and a favorable microenvironment for skin repair. CYGNUS Dual has inherent properties that ensure wound adherence, enabling the graft to adhere to the wound without fixation. Steri-strips can be used to hold the graft in place, if desired.

VIVEX's Integrity Processing™ methodology maintains the natural extracellular matrix scaffold. CYGNUS Dual also retains carbohydrates, growth factors, and cytokines, which can provide structural and biochemical support to the appropriate cells required for successful tissue repair.

INTENDED USE

CYGNUS Dual is an amniotic membrane graft, intended for use as a biological membrane covering that provides an extracellular matrix scaffold. CYGNUS Dual supports the patient's ability to repair underlying damaged tissue, such as acute and chronic wounds, including diabetic foot ulcers and venous ulcers.

CONTRAINDICATIONS

CYGNUS Dual should not be used in areas with severe vascular compromise or with active or latent infection or in a patient with a disorder that would create an unacceptable risk of post-operative complications.

DONOR ELIGIBILITY

CYGNUS Dual is obtained with consent from mothers during childbirth. The tissue that comprises CYGNUS Dual is acquired from the placenta from a qualified donor and processed using aseptic techniques in accordance with federal, state, and/or international regulations and to the standards of the American Association of Tissue Banks. The 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 of Vivex Biologics, Inc., and the donor has been deemed suitable for transplantation.

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 Plus O Antibodies (HIV-1/2 Plus O 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)

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

West Nile Virus (WNV)
- Nucleic Acid Test for WNV RNA (WNV NAT)

*A donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, is cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Screening tests for exposure to other viruses or parasites such as those listed below may or may not have been completed. A negative/nonreactive result may not be required for these tests; however, all results are evaluated on a case-by-case basis by the Medical Director of VIVEX Biologics.

Cytomegalovirus**
- CMV Ab (IgG & IgM)

Epstein Barr Virus
- EBV Ab (IgG & IgM)

Human T Cell Lymphotropic Virus I/II**
- HTLV-I/II (Antibody HTLV-I/II-Ab)

Toxoplasma gondii
- Toxoplasma Ab (IgG & IgM)

Trypanosoma cruzi
- T. cruzi Ab (IgG & IgM)

Zika Virus
- Zika Ab (IgM)
- Nucleic Acid Test for Zika RNA (Zika NAT)

**A donor with a reactive result for the CMV or HTLV-I/II Antibody test is cleared for transplantation use only when the result from a confirmatory assay is nonreactive.

WARNINGS

The donor of CYGNUS Dual is screened and tested for relevant communicable diseases and disease agents, and the tissue is microbiologically tested. CYGNUS Dual is processed using aseptic techniques and is terminally sterilized by electron beam irradiation validated in accordance with ANSI/AAMI/ISO 11137. Although 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. CYGNUS Dual may transmit infectious agents.

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.

DO NOT USE ALLOGRAFT IF EXPIRED.

ADVERSE EVENTS AND REACTIONS

Possible adverse events may include:

- Immunologic response (the possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells)
- Transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, syphilis, or microbial contaminants
- Infection of soft tissue and/or bone (osteomyelitis)
- Fever

STORAGE

CYGNUS Dual must be stored at ambient temperature (2°C to 30°C). 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, and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

PRECAUTIONS

CYGNUS Dual is processed and packaged using aseptic techniques and terminally sterilized. The allograft must be handled in an aseptic manner to prevent contamination.

CYGNUS Dual is packaged in an inner tear pouch within an outer peel pouch and secured in an outer box to ensure allograft integrity. Do not use the allograft if either pouch integrity has been compromised.

Use caution when opening, as CYGNUS Dual is a semi-transparent membrane.

Once the allograft container seal has been compromised, the allograft should be transplanted, if appropriate, or otherwise appropriately discarded.

The outermost pouch is not sterile and should not be placed on an operative field.

Do not rehydrate CYGNUS Dual prior to use.

ALLOGRAFT PREPARATION

Step 1: Remove the pouch containing the allograft from the box.

Step 2: Inspect the pouch for any holes, tears or incomplete seals.

Step 3: Using aseptic technique, peel open the outer peel pouch from the chevron end and present the inner pouch to the operative field, when required.

Step 4: Wait to open the inner pouch until ready to place the allograft. Locate the tear notch on the pouch and tear open using caution, as CYGNUS Dual is a semi-transparent membrane.

Step 5: Grasp the allograft and place it directly on the surgical or wound site.

Step 6: CYGNUS Dual is intended to remain on the wound as long as wound healing is progressing. After one or two weeks, the amniotic tissue will be incorporated into the wound. If there is a lack of sustained clinical progress, you may need to apply an additional graft.

RECIPIENT INFORMATION

Patient records must be maintained for the purpose of traceability. It is the responsibility of the end-user clinician to provide VIVEX Biologics with information pertaining to the traceability of the allograft used. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, peel off the small product labels provided on the product packaging and affix them on the TUR card and applicable patient records. Complete the TUR card and mail to VIVEX Biologics, scan and e-mail to turs@VIVEX.com, or fax to (888) 630-4321.

ADVERSE REACTION OUTCOME AND COMPLAINT REPORTING

Adverse reaction outcomes potentially attributable to the allograft or other complaints must be promptly reported to VIVEX Biologics at (888) 684-7783.

RETURNED GOODS POLICY

Due to the delicate biological nature of a processed allograft, it cannot be returned for credit. If for any reason the allograft must be returned, a return authorization is required from VIVEX Biologics prior to shipping. It is the responsibility of the health care institution returning the allograft to adequately package and label it for return shipment.

VIVEX Biologics warrants that the allograft will conform to the specifications set forth herein provided that the allograft is handled, stored, and implanted by health care providers according to the requirements set forth herein or as provided by VIVEX Biologics in writing. VIVEX Biologics makes no other warranties regarding the allograft and specifically disclaims any implied or statutory warranties, including any warranty against disease transmission and infection. Additionally, VIVEX Biologics makes no representations or warranties concerning the biological properties or biomechanical properties of the allograft.

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