GEO UmbiliCORD-C, Patch

DONATED HUMAN TISSUE

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

80-450 Rev. 01

GEO UmbiliCORD-C Patch is a semi-transparent, collagenous membrane allograft obtained with consent from healthy mothers during cesarean section delivery. GEO UmbiliCORD-C is derived from the umbilical cord.

GEO UmbiliCORD-C is processed using aseptic techniques and exposed to an antibiotic solution (containing Gentamicin and either Vancomycin or Bacitracin). It is then cryopreserved with a 100% polyampholyte-based cryoprotectant. The allograft is aseptically packaged in a jar inside of a tear pouch within a peel pouch configuration and secured in an outer container.

INTENDED USE

GEO UmbiliCORD-C is intended for use as a soft tissue barrier or wound covering.

CONTRAINDICATIONS

GEO UmbiliCORD-C is contraindicated in patients with known sensitivities to Gentamicin, Vancomycin, Bacitracin or polyampholytes.

DONOR ELIGIBILITY

GEO UmbiliCORD-C was recovered 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 has been 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 VIVEX Biologics, Inc. and the donor has been deemed suitable for transplantation.

Communicable disease testing has been performed on each donor 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)

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)

*A donor with a reactive result for the HTLV-I/II Antibody test is cleared for transplantation use only when the result from a confirmatory assay is nonreactive.
**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 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 (or licensed physician designee) of VIVEX Biologics, Inc.

Cytomegalovirus
CMV Ab (IgG & IgM)

Epstein Barr Virus
EBV Ab (IgG & IgM)

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)

WARNINGS

The donor of the GEO UmbiliCORD-C has been screened and tested for relevant communicable diseases and disease agents in compliance with the FDA regulations, relating to human cells, tissues, and cellular and tissue-based products (21 CFR Part 1271). The GEO UmbiliCORD-C was processed using aseptic techniques and microbiologically tested. 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. GEO UmbiliCORD-C may transmit infectious agents.

DO NOT RE-FREEZE the allograft by any method.

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

DO NOT 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.

ADVERSE EVENTS AND REACTIONS

Allogenic cells or tissues can induce an immunologic response in the recipient. 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.
Possible adverse events may include: immunologic response, transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants.

STORAGE

GEO UmbiliCORD-C must be stored at -65˚C or colder. 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

The GEO UmbiliCORD-C is processed and packaged using aseptic techniques. The GEO UmbiliCORD-C must be handled in an aseptic manner to prevent contamination.

DO NOT USE THE ALLOGRAFT if the pouch integrity has been compromised.

ONCE THE ALLOGRAFT CONTAINER SEAL HAS BEEN COMPROMISED, the allograft shall be transplanted within 2 hours of thawing, or otherwise discarded.

THE CHEVRON PEEL POUCHES ARE NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

- Outermost package is a protective covering for product component(s).
- Only contents of individual product component(s) should be presented to the operative field.

ALLOGRAFT PREPARATION

Step 1: Prepare a sterile saline or sterile water bath for thawing of the allograft (see Step 5).
Step 2: Remove the chevron peel pouch containing the allograft from the outer packaging.
Step 3: Utilizing aseptic technique, peel open the outer peel pouch from the chevron end and present the inner pouch to the operative field.
Step 4: Locate the tear notch on the inner pouch and remove the jar containing the allograft from the inner pouch using standard aseptic technique.
Step 5: Place the jar in the bath for 3-5 minutes or until the allograft has completely thawed.
Step 6: Rinse the allograft in sterile warm saline.
Step 7: Grasp the allograft and place it directly on the surgical or wound site.

RECIPIENT INFORMATION

Patient records must be maintained for the purpose of traceability. It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain recipient records for the purpose of tracing tissue post-transplantation and to provide VIVEX Biologics, Inc. 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 on the TUR card and applicable patient records. Complete the TUR card and mail to VIVEX Biologics, Inc., scan and e-mail to turs@VIVEX.com, or fax to (888) 630-4321.

ADVERSE REACTION OUTCOME AND COMPLAINT REPORTING

Adverse reactions outcomes potentially attributable to GEO UmbiliCORD-C or other complaints must be promptly reported to VIVEX Biologics, Inc. 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, Inc. prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

Distributed by:

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