Complete AA™ Membrane

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).

STERILE R
Sterilized by Irradiation

The COMPLETE AA™ membrane is a semi-transparent, collagenous dual layer amniotic membrane allograft obtained with consent from healthy mothers during cesarean section delivery. The COMPLETE AA™ membrane is derived from placental tissue.

The COMPLETE AA™ membrane is processed using aseptic techniques, treated with a buffered salt and detergent solution, and dehydrated. The allograft is aseptically packaged in a peel pouch within a peel pouch configuration. The allograft has been sterilized using radiation and secured in an outer container.

INTENDED USE

The COMPLETE AA™ membrane is intended to serve as a barrier and provide protective coverage from the surrounding environment for acute and chronic wounds. COMPLETE AA™ may be applied from the onset of the wound and for the duration of the wound, weekly or at the discretion of the health care practitioner.

CONTRAINDICATIONS

The COMPLETE AA™ membrane should not be used on (1) areas with active or latent infection and/or (2) a patient with a disorder that would create an unacceptable risk to their health while using this product. This allograft has not been tested in combination with other products.

DONOR ELIGIBILITY

COMPLETE AA™ membrane is recovered from qualified donors 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. 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 Xtant Medical and the donors have been deemed eligible 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 Antibodies (HIV-1/2-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)

*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 is not required for these tests; however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee).

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)

WARNINGS

The donors of COMPLETE AA ™ are 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). COMPLETE AA ™ is processed using aseptic techniques and microbiologically tested. The allograft has been terminally sterilized by 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.

PRECAUTIONS

COMPLETE AA ™ is processed and packaged using aseptic techniques and sterilized. The allograft must be handled in an aseptic manner to prevent contamination.

ADVERSE EVENTS

Allogeneic 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

COMPLETE AA ™ 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.

ALLOGRAFT PREPARATION

USE CAUTION WHEN OPENING. COMPLETE AA ™ IS A SEMI-TRANSPARENT MEMBRANE.

ONCE THE ALLOGRAFT CONTAINER SEAL HAS BEEN COMPROMISED, the allograft shall be transplanted within 24 hours, if appropriate, or otherwise discarded.

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

THE OUTERMOST POUCH IS NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

It is not necessary to rehydrate COMPLETE AA ™ prior to use.

Step 1: Inspect the pouch packaging.

Step 2: Utilizing aseptic technique, peel open the outer Tyvek peel pouch from the chevron end and present the inner foil pouch to the operative field, when required.

Step 3: Wait to open the inner pouch until ready to place the allograft. Utilizing aseptic technique, peel open the inner Foil peel pouch from the chevron end.

Step 4: Grasp the allograft and place it directly on the surgical or wound site.

Step 5: Anchor the graft using preferred method of fixation. Absorbable/nonabsorbable suture material and/or tissue adhesives may be used to apply the graft to the surgical or wound site, if necessary.

RECIPIENT INFORMATION

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide Samaritan 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 on the TUR card and applicable patient records. Complete the TUR card and return to Samaritan Biologics, Inc., scan and e-mail to info@samaritanbiologics.com or fax to (901) 254-8387.

ADVERSE OUTCOME AND COMPLAINT REPORTING

Adverse outcomes potentially attributable to COMPLETE AA ™ or other complaints must be promptly reported to Samaritan Biologics at (901) 254-8393.

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 Samaritan 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.

ADVANCED SOLUTION

Distributed By:
Advanced Solution
1 N. Hanover St.
Carlisle, PA 17013

Manufactured for Samaritan Biologics By:
Xtant Medical
664 Cruiser Lane
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