RAMPART
DUAL LAYER MATRIX

Amnion Membrane Sheet

PACKAGE INSERT/INSTRUCTIONS FOR USE

Description: Rampart Dual Layer Matrix is a human amniotic membrane sheet comprised of donated human tissue. The human amniotic membrane is derived from the placenta, and the product consists of a dual-layer amnion membrane. It is a minimally manipulated, dehydrated, non-viable cellular membrane, and there may be variations in color, opacity, and thickness due to the nature of the tissue. PRODUCT IS SUPPLIED STERILE.

Biocentric Lab
913 S. Main St. Suite 215,
Grapevine, TX 76051
www.biocentriclab.com

STERILE R

℞ Only

TISSUE USES

Rampart Dual Layer Matrix is intended for homologous use as a barrier and applied as a covering to offer protection from the surrounding environment.

PRECAUTIONS/WARNING

Rampart Dual Layer Matrix remains suitable for transplantation in an unopened, undamaged package under proper storage conditions.

Please inspect the integrity of the package upon receipt. If package and contents appear defective or damaged in any way, immediately contact the distributor.

This product is intended for single patient use only. Discard all unused material.

The procedure should be performed by an authorized medical professional.

Strict donor screening and laboratory testing, along with dedicated processing and sterilization methods, are employed to reduce the risk of any disease transmission. However, as with all biological product, an absolute guarantee of tissue safety is not possible. This product has the potential to transmit infectious disease to the recipient.

The reaction of the body to any biological product is not completely understood. Discard all damaged, mishandled, or potentially contaminated tissue.

This product has not been tested in combination with other products.

DO NOT RE-STERILIZE.

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Caution: U.S. Federal Law restricts this tissue to be sold by, or on the order of, a physician or hospital, and its use is limited to specific health professionals. Rampart Dual Layer Matrix CONTAINS A HUMAN CELLULAR AND TISSUE BASED PRODUCT (HCT/P) AS DEFINED IN US FDA TITLE 21 CFR PART 1271.
This product is voluntarily DONATED HUMAN TISSUE.

Rampart Dual Layer Matrix 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 of post-operative complications.

PREPARATION, RECONSTITUTION, USE

Prior to use, carefully follow the Rampart Dual Layer Matrix product preparation steps below using aseptic technique:

Removing Rampart Dual Layer Matrix from Packaging

The outer peel pouch is NOT sterile. The inner pouch that contains Rampart Dual Layer Matrix is sterile (unless the pouches are damaged or compromised).

Carefully open the peelable corner of the outer pouch and present the inner pouch onto the sterile field. Ensure the inner pouch does not come in contact with any portions of non-sterile surface of the outer pouch. In the sterile field, SLOWLY peel a corner of the inner peel pouch and grasp Rampart Dual Layer Matrix with fingers or non-toothed, sterile forceps.

Use Rampart Dual Layer Matrix promptly after opening the inner, sterile pouch. Once open, transplant or discard.

PLEASE TAKE GREAT CARE WHEN REMOVING THE Rampart Dual Layer Matrix FROM THE INTERNAL POUCH. THE PRODUCT IS THIN AND EXTREMELY LIGHTWEIGHT.

Rampart Dual Layer Matrix Application

In its dry state and prior to hydration, Rampart Dual Layer Matrix may be cut with sharp scissors to the appropriate and approximate size required.

The product should then be placed on the site.

The product can then be hydrated while on the site with a sterile saline solution.

Suture material (absorbable, non-absorbable) and/or tissue adhesives can be used to fixate Rampart Dual Layer Matrix to the site of application or itself, if desired.

Use product within 1 hour of reconstitution.

ADVERSE EVENTS AND REPORTING

As with any procedure, the possibility of infection exists. Proprietary processing and validated sterilization methods are employed to eliminate any potentially deleterious components of the product. However, as with all biological product, the possibility of rejection exists.

Adverse reactions, including the suspected transmission of disease attributable to this product, should be reported immediately to Biocentric Lab at (817) 329-4625.

ACCEPTABLE STORAGE

Rampart Dual Layer Matrix should be stored in a clean, dry environment at ambient conditions (15-30 °C). Check the label for the expiration date. The tissue dispensing service, tissue distribution intermediary, and/or end-user clinician must maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

RECOVERY AND QUALITY CONTROL

All tissue recovered meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. Rampart Dual Layer Matrix is procured and processed in the United States according to standards and/or regulations established by the American Association of Tissue Banks (AATB) and the United States Food & Drug Administration (FDA). All tissues are recovered under the full informed consent of the donors (mothers of the newborn children). The donors have consented to the transfer of the product to third parties. A thorough medical and social history of the donor is also obtained.

The communicable disease testing listed below was performed by an FDA-registered laboratory, certified to perform donor testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or by a laboratory that meets equivalent standards as determined by the Centers for Medicare and Medicaid Services (CMS):

HIV-1&2 Plus 0 Antibody	Hepatitis C Antibody
HIV Type 1 (Nucleic Acid Test (NAT))	Hepatitis C Virus (Nucleic Acid Test (NAT))
Hepatitis B Core Antibody	Hepatitis B Virus (Nucleic Acid Test (NAT))
Syphilis (Serologic Test)	West Nile Virus (Nucleic Acid Test (NAT))
Hepatitis B Surface Antigen	

Additional testing that may be performed:

HTLV-1&2 Antibody

All tests produced negative results and were reviewed prior to the release of the tissue. Only tissue from donors with acceptable test results, according to the standards of Biocentric Lab, as well as the standards and/or regulations of all state and federal regulatory bodies, are released.

The infectious disease test results, consent documents, donor medical history, behavior risk assessment according to current public health services guidelines, physical assessment, available relevant medical records, information from other sources or records that may pertain to donor suitability, and tissue procurement test results have been evaluated by the Biocentric Lab Medical Director and are sufficient to indicate that the donor suitability criteria current at the time of tissue recovery have been met.

The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of this product are on file and available upon request. This product has been determined to be suitable for transplantation. This product is voluntarily DONATED HUMAN TISSUE.

PRODUCT PROCESSING/PRESERVATION/ STERILIZATION

Rampart Dual Layer Matrix is processed based on strict, quality-controlled protocols that have demonstrated bioburden control.
An additional assurance of safety is achieved by terminally sterilizing each product. Based upon validations, each product has been effectively sterilized using E-Beam irradiation.

RECIPIENT TRACKING

The FDA requires that recipient records be maintained for the purpose of tracking the product following transplantation. The authorized medical professional must complete the enclosed Product Record, peel off and attach the product-tracking label provided, and forward to Biocentric Lab. Please use the remaining peel-off, product-tracking labels for patient and hospital records.

Caution: This product must be administered by an authorized medical professional.

The user shall be solely responsible for determining the adequacy and appropriateness of the product for any and all uses to which the user shall apply the product.

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Product processed by and
Donor eligibility determination by:

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