# AmnioAMP-MP™

AMNIOTIC ALLOGRAFT PATCH
DUAL-LAYER AMNION MEMBRANE SHEET
Package Insert/Instructions for Use

**Description**: AmnioAMP-MP™Amniotic Membrane Allograft is a human amniotic membrane sheet comprised of donated human tissue. The human amniotic membrane is derived from the placenta and the allograft 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. ALLOGRAFT IS SUPPLIED STERILE.

Stratus Biosystems, LLC dba
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Grapevine, TX 76051
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STERILE R 2 Rx only

AmnioAMP-MP™

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CellGenuity REGENERATIVE SCIENCE

Caution: U.S. Federal Law restricts this tissue to sale by or on the order of a physician hospital, and use to specific health professionals. THIS PRODUCT 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.

## TISSUE USES

AmnioAMP-MP™ is intended for homologous use as a barrier and applied as a covering to offer protection from the surrounding environment.

## PRECAUTIONS/WARNING

- AmnioAMP-MP™ allografts remain 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.
- These allografts are 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 grafts, an absolute guarantee of tissue safety is not possible. These allografts have the potential to transmit infectious disease to the recipient.
- The reaction of the body to any biological graft is not completely understood.
- Discard all damaged, mishandled, or potentially contaminated tissue.
- These products have not been tested in combination with other products.
- DO NOT RE-STERILIZE.

AmnioAMP-MP™ should not be used on (1) areas with active or latent infection and/or (2) into a patient with a disorder that would create an unacceptable risk of post-operative complications.

## PREPARATION, RECONSTITUTION, USE

Prior to use, carefully follow the AmnioAMP-MP™ allograft preparation steps below using aseptic technique:

### Removing AmnioAMP-MP™ from Packaging

- The outer peel pouch is NOT sterile. The inner pouch that contains AmnioAMP-MP™ 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 AmnioAMP-MP™ with fingers or non-toothed, sterile forceps.
- Use AmnioAMP-MP™ promptly after opening the inner, sterile pouch. Once open, transplant or discard.

**PLEASE TAKE GREAT CARE WHEN REMOVING THE PRODUCT FROM THE INTERNAL POUCH. THE ALLOGRAFT IS THIN AND EXTREMELY LIGHTWEIGHT**

### AmnioAMP-MP™ Application

- In its dry state and prior to hydration, the allograft may be cut with sharp scissors to the appropriate and approximate size required.

- The allograft should then be placed on the site.
- The allograft 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 AmnioAMP-MP™ allografts to the site of application or itself, if desired.
- Use graft 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 allograft. However, as with all biological grafts, the possibility of rejection exists.

Adverse reactions, including the suspected transmission of disease attributable to this allograft, should be reported immediately to Stratus Biosystems, LLC at (817) 329-4625.

## ACCEPTABLE STORAGE

AmnioAMP-MP™ allografts 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. AmnioAMP-MP™ allografts are 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 allografts to third parties. A thorough medical and social history of the donor is also obtained. The listed communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).
Each donor is screened for:

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| 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 Stratus Biosystems, LLC 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, as well as information from other sources or records that may pertain to donor suitability, and tissue procurement test results, have been evaluated by the Stratus Biosystems, LLC, 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 allograft are on file and available upon request. Donated Human Tissue. These allografts have been determined to be suitable for transplantation.

## ALLOGRAFT PROCESSING/PRESERVATION/STERILIZATION

AmnioAMP-MP™ allografts are processed based on strict, quality-controlled protocols that have demonstrated bioburden control. An additional assurance of safety is achieved by terminally sterilizing each allograft. Based upon validations, each graft has been effectively sterilized using E-Beam irradiation.

## RECIPIENT TRACKING

The FDA requires that recipient records be maintained for the purpose of tracking the allograft following transplantation. The authorized medical professional must complete the enclosed Transplant Utilization Record, attach a peel-off, allograft-tracking label provided, and forward to Stratus Biosystems, LLC. Please use the remaining peel-off, allograft-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 allograft for any and all uses to which the user shall apply the allograft.

Stratus BioSystems

Allograft tissue processed by and
Donor eligibility determination by:

**Stratus Biosystems, LLC**
913 S Main St Suite 215
Grapevine, TX 76051