BONEBANK®
ALLOGRAFTS

AMNIOS™ CRYOPRESERVED AMNION TISSUE PACKAGE INSERT

READ BEFORE USING

THIS AMNION & PLACENTA IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.

DESCRIPTION

Amnios™ is supplied by **BONE BANK ALLOGRAFTS** (BBA) and was processed and prepared by Texas Human Biologics (THB). All recovery, processing and distribution costs were reimbursed in part by **BONE BANK ALLOGRAFTS** in accordance with NOTA.

This allograft is supplied aseptically processed. Representative product from each lot undergoes destructive microbiological verification testing per USP <71> and must show "no growth" following 14 days on culture.

REGULATORY CLASSIFICATION

This allograft is a human tissue product for transplantation. It is processed and distributed in accordance with FDA requirements for Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271), State regulations, and the Standards of the American Association of Tissue Banks (AATB).

Caution: Federal Law restricts this product to sale by or on the order of a licensed practitioner.

APPLICATIONS FOR USE

This allograft may be used for different types of surgical procedures. It may be used independently or in combination with autologous tissue or other forms of allograft tissue.

This allograft is intended for single patient use only.

DONOR RECOVERY AND SCREENING

After authorization for donation is obtained, surgical recovery of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments. Donor eligibility is carefully evaluated as required by the US FDA and in accordance with AATB Standards and applicable State guidelines. Tissue donors are evaluated for high risk behaviors and relevant communicable diseases. Screening includes a review of the donor medical and social history, a physical assessment of the donor, an autopsy review (if performed), serological screening, tissue recovery microbiology, and cause of death.
Each donor is tested and shown to be **negative** or **nonreactive** for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- HIV1/HCV Nucleic Acid Test (NAT)
- Human T-Cell Lymphotropic Virus Type I Antibody (not required)
- Human T-Cell Lymphotropic Virus Type II Antibody (not required)

This testing is performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens under 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).

BONE BANK ALLOGRAFTS' Medical Director has determined this donor tissue to be suitable for transplantation**.** The testing and medical release records are maintained by **BONE BANK ALLOGRAFTS.**

PROCESSING

Amnios™ is processed in a controlled environment using methods designed to prevent contamination and cross contamination. Final products are sized and packaged according to approved specifications and procedures and are

Note: Amnios™ will naturally vary in color from pink, pale pink, and yellow to pale yellow.

CONTRAINDICATIONS

Contraindications for the use of this allograft shall be determined by a licensed practitioner.

WARNINGS

Careful donor screening, laboratory testing, tissue processing, and where applicable gamma irradiation have been utilized to minimize the risk of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this graft cannot be guaranteed to be free of all pathogens.

Do NOT place vial in sterile field. The outside of the vial is NOT sterile.

Do NOT reuse or sterilize.

Do NOT refreeze product if thawed.

PACKAGING AND LABELING

Each allograft distributed by **BONE BANK ALLOGRAFTS** is identified by its own unique serial number. Amnios™ is packaged in a vial and is supplied frozen. Contents of the vial have been processed aseptically and have passed testing according to USP <71> sterility tests.

Warning: If the innermost pouch is compromised or shows evidence of being torn or opened, **DO NOT USE**!

Amnios™ is supplied frozen.

TRANSPORT AND STORAGE OF FROZEN GRAFTS

Amnios™ is shipped frozen on dry ice via overnight courier. Upon arrival, product should be removed from the shipping container and placed in appropriate frozen storage at -70°C or colder.

EXPIRATION

See package label for expiration date or observe the above indications for alternate tissue storage.

It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to track expiration date accordingly.

USAGE INSTRUCTIONS

Before Usage: Examine Allograft Package – Do Not Use This Allograft If:

1. Any of the package or product elements appear to be missing, tampered with or damaged.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed.
4. Frozen allograft has not been stored according to storage temperature requirements or the allograft has been prematurely thawed.

If any of the above conditions exist or are suspected, this allograft should NOT be used.

Amnios™ is packaged in a sterile vial. The contents of the vial have been processed using an aseptic technique and have undergone destructive microbiological verification testing per USP <71> Sterility Tests. The test results must show ***"NO GROWTH"*** after 14 days.

Directions for Use:
Amnios™ is packaged in a sterile screw top vial. The outside of the vial or the peel pouch package containing the vial are ***NOT STERILE.*** *A*ppropriate handling is required to avoid contamination of the product or the sterile operative field.

Prepare the allograft for use using the following procedures:

1. Maintain at -70°C or colder until immediately prior to use. Open the container and remove the outer package, remove the peel pack containing the vial from the carton.
2. Open the peel pouch and remove the vial.
3. In a clean product field, place the closed vial in a sterile water or saline bath. Thaw the vial for 3-5 minutes until the contents of the vial are in a flowable liquid state.
4. Using aseptic technique, perform the following and remove the vial from the basin.
   - Remove the cap
   - Carefully remove or transfer the contents from the vial using aseptic handling technique

FROZEN TISSUES:
Note: Before use, the allograft must be thawed. The allograft must not be refrozen after thawing.

RETURNS

No Amnios™ returns will be accepted if the original container has been opened, the tamper evident seal has been compromised, or if the package has exceeded expiration of dry ice validation. All frozen tissue returns are at the sole discretion of Bone Bank Allografts.

PATIENT RECORD

Recipient records must be maintained for the purpose of tracking tissue post-transplant. ***IMPORTANT NOTICE TO END-USER****:* Please record this distinct graft identification code in your records and in the patient's medical record. It is also recommended that the following information be recorded in the patient's medical record:

1. Description of Tissue
2. Product Code
3. Expiration Date
4. Description of Procedure
5. Date and Time of Procedure
6. Surgeon Name
7. Any Other Pertinent Information

A Transplant Record has been included with each package of tissue. Please record the patient name, **distinct graft identification code**, date of birth, sex, name and address of the healthcare facility, name of the transplanting physician, date and type of surgery, name of the person filling out the Transplant Record and any comments. Once completed, the bottom copy of the Transplant Record should be returned to **BONE BANK ALLOGRAFTS**. Copies of this information should be retained by the transplant facility for future reference.

POTENTIAL COMPLICATIONS

Amnios™ contains allogeneic proteins (eg collagen) and cells which have the potential for hypersensitivity, allergic reactions or other immune responses. All adverse outcomes potentially attributed to the Amnios™ must be promptly reported to **BONE BANK ALLOGRAFTS.**

Possible complications can occur with any surgical procedure including, but not limited to pain, infection, hematoma, incomplete or lack of bony growth at treatment site, and/or immune rejection of the introduced tissue.

Disease screening methods are limited; therefore, certain diseases may not be detected.

The following complications of tissue transplantation may occur:

- Transmission of diseases of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.
- Immune reaction to implanted HCT/P

DISPOSAL

Allograft disposal shall be in accordance with local, state, and federal regulations for human tissue.

INQUIRIES

For additional information, to place an order, or to report adverse reactions, contact: **BONE BANK ALLOGRAFTS** Client Services at:

Phone: 800-397-0088
Fax: 210-696-7609

BONEBANK® ALLOGRAFTS

4808 RESEARCH DRIVE
SAN ANTONIO, TX 78240
(800) 397-0088
FDA Registration FEI: 3000779542

ALLOGRAFT TISSUE PROCESSED BY:
Texas Human Biologics
14805 Omicron Drive, Suite 200
San Antonio, Texas 78245

LB-268 R00 Eff. Date: October 16, 2015; CN# 15.161

BONEBANK® ALLOGRAFTS

AMNIOS™ RT AMNION TISSUE PACKAGE INSERT

READ BEFORE USING

THIS AMNION & PLACENTA IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.

DESCRIPTION

Amnios™ RT is supplied by **BONE BANK ALLOGRAFTS** (BBA) and was processed and prepared by Texas Human Biologics (THB). All recovery, processing and distribution costs were reimbursed in part by **BONE BANK ALLOGRAFTS** in accordance with NOTA.

This allograft is supplied sterile.

REGULATORY CLASSIFICATION

This allograft is a human tissue product for transplantation. It is processed and distributed in accordance with FDA requirements for Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271), State regulations, and the Standards of the American Association of Tissue Banks (AATB).

Caution: Federal Law restricts this product to sale by or on the order of a licensed practitioner.

APPLICATIONS FOR USE

This allograft may be used for different types of surgical procedures. It may be used independently or in combination with autologous tissue or other forms of allograft tissue.

This allograft is intended for single patient use only.

DONATED HUMAN TISSUE RECOVERY, SCREENING AND MEDICAL RELEASE DETERMINATION GUIDELINES

After authorization for donation is obtained, surgical recovery of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments. Donor eligibility is carefully evaluated as required by the US FDA and in accordance with AATB Standards and applicable State guidelines. Tissue donors are evaluated for high risk behaviors and relevant communicable diseases. Screening includes a review of the donor medical and social history, a physical assessment of the donor, an autopsy review (if performed), serological screening, tissue recovery microbiology, and cause of death.

Each donor is tested and shown to be **negative** or **nonreactive** for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- HIV1/HCV/HBV ULTRIO Nucleic Acid Test (NAT)
- Human T-Cell Lymphotropic Virus Type I Antibody (not required)
- Human T-Cell Lymphotropic Virus Type II Antibody (not required)
- WNV RNA Screen, PCR on our Placenta/Fluid donors

This testing is performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens under 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).

BONE BANK ALLOGRAFTS' Medical Director has determined this donor tissue to be suitable for transplantation**.** The testing and medical release records are maintained by **BONE BANK ALLOGRAFTS.**

PROCESSING

Amnios™ RT is processed in a controlled environment using methods designed to prevent contamination and cross contamination. Final products are packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 standards.

Note: Amnios™ RT will naturally vary in color from pink to pale pink, yellow to pale yellow, or clear.

CONTRAINDICATIONS

Contraindications for the use of this allograft shall be determined by a licensed practitioner.

WARNINGS

Careful donor screening, laboratory testing, tissue processing, and gamma irradiation have been utilized to minimize the risk of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this graft cannot be guaranteed to be free of all pathogens.

Do NOT reuse or re-sterilize.

PACKAGING AND LABELING

Each allograft distributed by **BONE BANK ALLOGRAFTS** is identified by its own unique serial number. Amnios™ RT is packaged in a vial, sealed in a peel back pouch, and terminally sterilized. Contents of the package are sterile unless the package is opened or damaged.

Warning: If the innermost pouch is compromised or shows evidence of being torn or opened, **DO NOT USE**!

Amnios™ RT is supplied at room temperature.

TRANSPORT AND STORAGE

Amnios™ RT may be stored at room temperature (15-30°C or 59-86° F). It is not necessary to refrigerate or freeze Amnios™ RT.

EXPIRATION

See package label for expiration date or observe the above indications for alternate tissue storage.

It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to track expiration date accordingly.

USAGE INSTRUCTIONS

Before Usage: Examine Allograft Package – Do Not Use This Allograft If:

1. Any of the package or product elements appear to be missing, tampered with or damaged.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed.

If any of the above conditions exist or are suspected, this allograft should NOT be used.

Directions for Use:

Amnios™ RT fluid is provided sterile. The outside of the vial and the inner peel pouch containing the vial are sterile**.**

RETURNS

No Amnios™ RT returns will be accepted if the original container has been opened, the tamper evident seal has been compromised, or if the package has exceeded expiration.

PATIENT RECORD

Recipient records must be maintained for the purpose of tracking tissue post-transplant. ***IMPORTANT NOTICE TO END-USER:*** Please record this distinct graft identification code in your records and in the patient's medical record. It is also recommended that the following information be recorded in the patient's medical record:

1. Description of Tissue
2. Product Code
3. Expiration Date
4. Description of Procedure
5. Date and Time of Procedure
6. Surgeon Name
7. Any Other Pertinent Information

A Transplant Record has been included with each package of tissue. Please record the patient name, **distinct graft identification code**, date of birth, sex, name and address of the healthcare facility, name of the transplanting physician, date and type of surgery, name of the person filling out the Transplant Record and any comments. Once completed, the bottom copy of the Transplant Record should be returned to **BONE BANK ALLOGRAFTS**. Copies of this information should be retained by the transplant facility for future reference.

POTENTIAL COMPLICATIONS

Amnios™ RT contains allogeneic proteins which have the potential for hypersensitivity, allergic reactions or other immune responses. All adverse outcomes potentially attributed to the Amnios™ RT must be promptly reported to **BONE BANK ALLOGRAFTS.**

Possible complications can occur with any surgical procedure including, but not limited to pain, infection, hematoma, incomplete or lack of bony growth at treatment site, and/or immune rejection of the introduced tissue.

Disease screening methods are limited; therefore, certain diseases may not be detected.

The following complications of tissue transplantation may occur:

- Transmission of diseases of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.
- Immune reaction to implanted HCT/P

DISPOSAL

Allograft disposal shall be in accordance with local, state, and federal regulations for human tissue.

INQUIRIES

For additional information, to place an order, or to report adverse reactions, contact: **BONE BANK ALLOGRAFTS** Client Services at:

Phone: 800-397-0088
Fax: 210-696-7609

BONEBANK® ALLOGRAFTS

4808 RESEARCH DRIVE
SAN ANTONIO, TX 78240
(800) 397-0088
FDA Registration FEI: 3000779542

ALLOGRAFT TISSUE PROCESSED BY:
Texas Human Biologics
14805 Omicron Drive, Suite 200
San Antonio, Texas 78245

LB-313 R00 Eff. Date: January 17, 2017; CN# 16.085