ROOM TEMPERATURE AMNIOTIC FLUID ALLOGRAFT TISSUE PACKAGE INSERT AND RECONSTITUTION INFORMATION

READ BEFORE USING

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. PROCESSING AND PACKAGING WERE ASEPTICALLY COMPLETED IN A CLEANROOM FACILITY. STERILIZATION VIA GAMMA IRRADIATION WAS USED IN THE PROCESS.

DESCRIPTION AND APPLICATIONS FOR USE

Amniotic fluid is a minimally processed allograft. **This allograft shall be used exclusively as part of the clinical study for the treatment of plantar fasciitis.**

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. Human Tissue for transplant shall not be offered, distributed or dispensed for veterinary use.

DONOR ACQUISITION AND SCREENING

After legal authorization or consent for donation is obtained, acquisition of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments.

Blood samples from each donor are tested 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). Test kits used are approved by the FDA for testing cadaveric specimens where applicable. Donor test results were shown to be **negative** or **nonreactive** for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- HIV1 Nucleic Acid Test (NAT)
- Hepatitis C Virus Antibody
- HCV Nucleic Acid Test (NAT)
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- HBV Nucleic Acid Test (NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- West Nile Virus Nucleic Acid Test (WNV NAT)

Internationally distributed tissues only:

- Human T-Cell Lymphotropic Virus Type I and II Antibody

Donor medical and social history, physical assessment, autopsy results (if performed), infectious disease testing, tissue cultures, cause of death and all other available medical records have been evaluated by a licensed physician and determined to meet all donor eligibility requirements for transplantation as required by the US FDA and in accordance with AATB Standards and applicable State guidelines. All testing and medical release records are maintained by Bone Bank Allografts.

PROCESSING

Allograft tissues are processed in a controlled cleanroom environment using methods designed to prevent contamination and cross contamination. A 10% low molecular weight Dextran (LMD) in 5% Dextrose radioprotectant solution is used during packaging. Antibiotics were not used in the processing of these allografts. Final products are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 standards.

Allograft tissues will naturally vary in color from yellow to pale yellow, or clear.

WARNINGS AND PRECAUTIONS

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

Possible complications can occur with any medical procedure including, but not limited to pain, bacterial infection, or transmission of diseases of unknown etiology. As allografts are composed of allogeneic proteins, the potential for hypersensitivity, allergic reactions or other immune responses may exist.

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

All adverse outcomes potentially attributed to the allograft must be promptly reported to Bone Bank Allografts and to the Distributor listed on the container label, if applicable.

This allograft is intended for single patient use only.
Do NOT reuse or sterilize.
Do NOT freeze product.

Do Not Use This Allograft If:

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

PACKAGING AND LABELING

Amniotic fluid allografts are supplied at room temperature. Each allograft is identified by its own unique serial number and packaged in a plastic vial placed in a two-layer pouch configuration.

The package container label includes graft details such as distributor name, address, phone number and product dimensions and/or volumes. **Contents of the package are sterile unless the package is opened or damaged.**

TRANSPORT, STORAGE AND EXPIRATION

Product is shipped at ambient temperatures. Upon receipt product should be removed from the shipping container and stored at room temperature (59-86°F or 15-30°C). No refrigeration is necessary.

See package label for expiration date.

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

Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or properly discarded.

1. Open allograft packaging for use by following the below procedures. Use proper aseptic technique to open and deliver the allograft to the sterile field:

   a) Cut or tear open the non-sterile outermost moisture barrier and remove associated labeling materials.
   b) Peel open the outer pouch and deliver the innermost sterile sealed pouch containing the graft material to a sterile field.
   c) Peel open the sterile sealed pouch and deliver the graft vial to a sterile field.
   d) Remove cap of vial.
   e) Carefully remove or transfer the contents from the vial using aseptic handling technique.
   f) Apply fluid to site.

Allograft must be used within six hours after preparing if the allograft is stored at room temperature. If refrigerated and stored between 2°C and 8°C within six hours after preparing, the allograft may be used within 24 hours. Graft must be stored with proper precautions to prevent contamination.

If for any reason the graft is opened and not used, it should be disposed of properly in accordance with recognized local, state, and federal regulations for discarding medical waste material. Document the reason for the non-use of the graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to the address listed.

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. Expiration Date
3. Description of Procedure
4. Date and Time of Procedure
5. Surgeon Name
6. 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 procedure, 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 the address indicated. Copies of this information should be retained by the transplant facility for future reference.

Donor Eligibility Determination and Processing By:
Bone Bank Allografts
5335 Castroville Road
San Antonio, TX 78227
(800) 397-0088
FDA Registration FEI: 3000779542
All acquisition, processing and distribution costs were reimbursed in part by Bone Bank Allografts in accordance with NOTA

AMNIOTIC MEMBRANE ALLOGRAFT TISSUE PACKAGE INSERT AND RECONSTITUTION INFORMATION

READ BEFORE USING

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. PROCESSING AND PACKAGING WERE ASEPTICALLY COMPLETED IN A CLEANROOM FACILITY. STERILIZATION VIA GAMMA IRRADIATION WAS USED IN THE PROCESS.

DESCRIPTION AND APPLICATIONS FOR USE

Human amniotic membrane is a thin collagenous membrane derived from the submucosa of the placenta, the area in which the human fetus grows and develops within the mother's uterus. Human amniotic membrane consists of collagen layers including: (1) basement membrane and (2) stromal matrix.
Membrane grafts are provided in a number of sizes and shapes to be used at the discretion of qualified medical professionals (e.g. physicians, dentists and/or podiatrists) as a wound covering in various procedures. They may be used independently or in combination with autologous tissue or other forms of allograft tissue.

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. Human Tissue for transplant shall not be offered, distributed or dispensed for veterinary use.

DONOR ACQUISITION AND SCREENING

After legal authorization or consent for donation is obtained, acquisition of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments.

Blood samples from each donor are tested 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). Test kits used are approved by the FDA for testing cadaveric specimens where applicable. Donor test results were shown to be **negative** or **nonreactive** for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- HIV1 Nucleic Acid Test (NAT)
- Hepatitis C Virus Antibody
- HCV Nucleic Acid Test (NAT)
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- HBV Nucleic Acid Test (NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- West Nile Virus Nucleic Acid Test (WNV NAT)

Internationally distributed tissues only:

Human T-Cell Lymphotropic Virus Type I and II Antibody

Donor medical and social history, physical assessment, autopsy results (if performed), infectious disease testing, tissue cultures, cause of death and all other available medical records have been evaluated by a licensed physician and determined to meet all donor eligibility requirements for transplantation as required by the US FDA and in accordance with AATB Standards and applicable State guidelines. All testing and medical release records are maintained by Bone Bank Allografts**.**

PROCESSING

Allograft tissues are processed in a controlled cleanroom environment using methods designed to prevent contamination and cross contamination. Proprietary physiological buffers, alcohols and surfactants are used during processing. Allograft tissue may contain traces of these processing agents. Antibiotics were not used in the processing of these allografts. Final products are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 standards.

Allograft tissues will naturally vary in color from white, off-white, pink, pale pink, and yellow to pale yellow. Occasional dark spots or localized discoloration are normal occurrences.

WARNINGS AND PRECAUTIONS

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

Possible complications may occur with any procedure including, but not limited to pain, bacterial infection, or transmission of diseases of unknown etiology. As allografts are composed of proteins such as collagen, the potential for hypersensitivity, allergic reactions or other immune responses may exist.

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

All adverse outcomes potentially attributed to the allograft must be promptly reported to Bone Bank Allografts and to the Distributor listed on the container label, if applicable.

This allograft is intended for single patient use only.
Do NOT reuse or sterilize.
Do NOT refreeze product if thawed.

Do Not Use This Allograft If:

1. Any of the package or product elements appear to be missing, tampered with or damaged.
2. Product label or identifying bar code is severely damaged, illegible or missing.
3. Expiration date shown on the package label has passed.
4. Allograft has not been stored according to storage temperature requirements.
5. Allograft has been thawed or rehydrated and not used within 24 hours.

PACKAGING AND LABELING

Amniotic Membrane Allografts are supplied desiccated. Each allograft is identified by its own unique serial number and packaged in a two-layer pouch configuration.

The package container label includes graft details such as distributor name, address, phone number and product dimensions and/or volumes. **Contents of the package are sterile unless the package is opened or damaged.**

TRANSPORT, STORAGE AND EXPIRATION

Desiccated tissues are shipped at ambient temperatures. Upon receipt product should be removed from the shipping container and stored at room temperature (59-86°F or 15-30°C). No refrigeration is necessary.

See package label for expiration date.

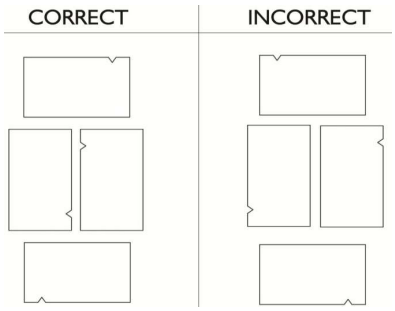
It is the responsibility of the end-user to maintain this allograft in the appropriate storage conditions prior to transplant and to track expiration date accordingly.

USAGE INSTRUCTIONS

Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or properly discarded.

1. Open allograft packaging for use by following the below procedures. Use proper aseptic technique to open and deliver the allograft to the sterile field:

   a) Cut or tear open the non-sterile outermost moisture barrier and remove associated labeling materials.
   b) Peel open the outer pouch and deliver the innermost sterile sealed pouch containing the graft material to a sterile field.
   c) Peel open the sterile sealed pouch and deliver the graft to a sterile field. **Please use caution when removing the allograft as they are very thin and extremely lightweight.**
   d) The allograft may be cut or shaped to the appropriate size required prior to placement on the wound site.
   e) Orientation for placement
      - **Dual Layer Amniotic Membrane Allografts**: There is no specific orientation required for placement.
      - **Single Layer Amniotic Membrane Allografts**: Use the orientation notch as a guide. Proper orientation (Epithelial side up) is achieved when the graft is held with the notch positioned on the upper right hand side of the allograft.
      - **It is recommended that the allograft be applied dry for ease of use.**



   f) Absorbable/non-absorbable suture material and/or tissue adhesives may be used to apply the graft to the application site, if necessary.
   g) Once applied to the site, the allograft can be hydrated with sterile saline or other sterile solution, if needed, or as necessary to smooth or reposition the allograft.

Allograft must be used within six hours after preparing if the allograft is stored at room temperature. If refrigerated and stored between 2°C and 8°C within six hours after preparing, the allograft may be used within 24 hours. Graft must be stored with proper precautions to prevent contamination.

If for any reason the graft is opened and not used, it should be disposed of properly in accordance with recognized local, state, and federal regulations for discarding medical waste material. Document the reason for the non-use of the graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to the address listed.

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 the address indicated. Copies of this information should be retained by the transplant facility for future reference.

Donor Eligibility Determination and Processing By:
Bone Bank Allografts
5335 Castroville Road
San Antonio, TX 78227
(800) 397-0088
FDA Registration FEI: 3000779542

All acquisition, processing and distribution costs were reimbursed in part by Bone Bank Allografts in accordance with NOTA.

ALLOGRAFT TISSUE PACKAGE INSERT AND RECONSTITUTION INFORMATION

READ BEFORE USING

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES. PROCESSING AND PACKAGING WERE ASEPTICALLY COMPLETED IN A CLEANROOM FACILITY. STERILIZATION VIA GAMMA IRRADIATION WAS USED IN THE PROCESS.

DESCRIPTION AND APPLICATIONS FOR USE

This processed human bone or soft tissue allograft is provided in a diverse range of sizes and shapes to be used at the discretion of qualified medical professionals (e.g. physicians, dentists and/or podiatrists) for various types of surgical procedures. It may be used independently or in combination with autologous tissue or other forms of allograft tissue.

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. Human Tissue for transplant shall not be offered, distributed or dispensed for veterinary use.

DONOR RECOVERY AND SCREENING

After legal authorization or consent for donation is obtained, recovery of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments.

Blood samples from each donor are tested 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). Test kits used are approved by the FDA for testing cadaveric specimens where applicable. Donor test results were shown to be **negative** or **nonreactive** for the following:

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- HIV1 Nucleic Acid Test (NAT)
- Hepatitis C Virus Antibody
- HCV Nucleic Acid Test (NAT)
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- HBV Nucleic Acid Test (NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay

Internationally distributed tissues only:

- Human T-Cell Lymphotropic Virus Type I and II Antibody

Donor medical and social history, physical assessment, autopsy results (if performed), infectious disease testing, tissue cultures, cause of death and all other available medical records have been evaluated by a licensed physician and determined to meet all donor eligibility requirements for transplantation as required by the US FDA and in accordance with AATB Standards and applicable State guidelines. All testing and medical release records are maintained by Bone Bank Allografts**.**

PROCESSING

Allograft tissues are processed in a controlled cleanroom environment using methods designed to prevent contamination and cross contamination. Proprietary physiological buffers, acids, alcohols and surfactants are used during processing. Allograft tissue may contain traces of these processing agents. Antibiotics were not used in the processing of these allografts. Final products are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 standards.

Allograft tissues will naturally vary in color from white, off-white, pink, pale pink, and yellow to pale yellow. Occasional dark spots or localized discoloration are normal occurrences.

WARNINGS AND PRECAUTIONS

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.

Possible complications may occur with any surgical procedure including, but not limited to pain, bacterial infection, hematoma, incomplete or lack of bony growth at treatment site, and/or immune rejection of the introduced tissue. As allografts are composed of proteins such as collagen, the potential for hypersensitivity, allergic reactions or other immune responses may exist.

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

All adverse outcomes potentially attributed to the allograft must be promptly reported to Bone Bank Allografts and to the Distributor listed on the container label, if applicable.

This allograft is intended for single patient use only.
Do NOT reuse or sterilize.
Do NOT refreeze product if thawed.

Do Not Use This Allograft If:

1. Any of the package or product elements appear to be missing, tampered with or damaged.
2. Product label or identifying bar code is severely damaged, illegible or missing.
3. Expiration date shown on the package label has passed.
4. Allograft has not been stored according to storage temperature requirements.
5. Allograft has been thawed or rehydrated and not used within 24 hours.

PACKAGING AND LABELING

Allografts are supplied frozen and/or freeze-dried. Each allograft is identified by its own unique serial number and packaged in a two-layer pouch configuration. Some allografts may also be placed in a vial container prior to packaging. If present, the tissue must be removed from the container prior to implantation.

The package container label includes graft details such as distributor name, address, phone number and product dimensions and/or volumes. **Contents of the package are sterile unless the package is opened or damaged.**

TRANSPORT, STORAGE AND EXPIRATION

Frozen product is shipped frozen on dry ice. Upon arrival, product should be removed from the shipping container and placed in a freezer at or below -40°C (-40°F). Frozen product may also be stored for 6 months or less from -20°C to -39°C (-4°F to -38°F).

Freeze dried tissues are shipped at ambient temperatures. Upon receipt product should be removed from the shipping container and stored at room temperature (59-86°F or 15-30°C). No refrigeration is necessary.

See package label for expiration date.

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

Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or properly discarded.

1. Open allograft packaging for use by following the below procedures. Use proper aseptic technique to open and deliver the allograft to the sterile field:

   a) Cut or tear open the non-sterile outermost moisture barrier and remove associated labeling materials.
   b) Peel open the outer pouch and deliver the innermost sterile sealed pouch containing the graft material to a sterile field.
   c) Peel open the sterile sealed pouch and deliver the graft to a sterile field.
   Vial Containers: Remove plastic cap and place the contents of the vial on the sterile field.

   Note: Weight bearing tissues or allografts which will be cut, shaped, sutured, shall not have excessive force applied during manipulation or implantation.

If for any reason the graft is opened and not used, it should be disposed of properly in accordance with recognized local, state, and federal regulations for discarding medical waste material. Document the reason for non-use of the graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to the address listed.

FREEZE DRIED TISSUES:

1. Immerse the allograft in sterile saline (0.9%), Lactated Ringer's, or other sterile isotonic solution for a minimum of 60 minutes.

   Note: Flexible partially demineralized cancellous sponge, cortical strip and cortical fiber products require a shorter rehydration time, and may be determined ready for use per surgeon's preference.

2. Extended rehydration time (up to 4 hours) is recommended for any tissue to be cut, shaped or wedged to reduce the chance of fracturing.
3. Allografts must be used within six (6) hours after rehydrating if the allograft is stored at room temperature. If refrigerated and stored between 2º C and 8º C within six hours after rehydrating, the allograft may be used within 24 hours (including rehydration time). Graft must be stored with proper precautions to prevent contamination.

FROZEN TISSUES:

1. Immerse the allograft in sterile saline (0.9%), Lactated Ringer's, or other sterile isotonic solution for 30 to 60 minutes. The **solution** used for thawing may be warmed to a maximum of 40ºC for thawing.
2. Allografts must be used within six (6) hours after thawing if the allograft is stored at room temperature. If refrigerated between 2º C and 8º C within six hours after thawing, the allograft may be used within 24 hours (including thaw time), if stored with proper precautions to prevent contamination. Allografts must not be refrozen.

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 the address indicated. Copies of this information should be retained by the transplant facility for future reference.

Donor Eligibility Determination and Processing By:
Bone Bank Allografts
5335 Castroville Road
San Antonio, TX 78227
(800) 397-0088
FDA Registration FEI: 3000779542

All recovery, processing and distribution costs were reimbursed in part by Bone Bank Allografts in accordance with NOTA