Spineology
anatomyconservingsurgery™

DBM PUTTY AND CRUNCH PACKAGE INSERT AND INSTRUCTIONS FOR USE

PROCESSED ALLOGRAFT TISSUE PACKAGE INSERT

READ BEFORE USING

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.

DESCRIPTION

This human tissue allograft is supplied by **Spineology** and was processed and prepared by Texas Human Biologics (THB). All recovery, processing and distribution costs were reimbursed in part by **Spineology** in accordance with NOTA.

This allograft is supplied sterile.

REGULATORY CLASSIFICATION

Incite DBM Putty and Crunch is a human tissue product for transplantation. They are 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 guidelines of the American Association of Tissue Banks (AATB).

APPLICATIONS FOR USE

Incite DBM Putty and Crunch are indicated for use in bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. These products provide a bone graft substitute that remodels into the recipient's skeletal system. 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). Test kits used are approved by the FDA for testing cadaveric specimens where applicable.

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

Allograft tissues are processed in a controlled 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. Final products are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 guidelines.

Note: 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 is a normal occurrence.

CONTRAINDICATIONS

Incite DBM and Crunch Putty is contraindicated where these products are intended as structural support in load-bearing bone and in articulating surfaces. Other conditions representing relative contraindication include:

- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors

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 **SPINEOLOGY**is identified by its own unique serial number. Each Allograft is individually sealed in a peel back pouch and terminally sterilized. .The package label includes graft details such as dimensions and/or volumes. 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!**

Incite DBM and Crunch Putty are supplied prehydrated and ready to use.

STORAGE OF INCITE DBM

Maintain allograft at room temperature (15-30°C or 59-86°F). It is not necessary or recommended to refrigerate or freeze Incite DBM and Crunch Putty. If allograft is refrigerated or frozen it must be thawed and warmed to room temperature prior to use. DO NOT EXPOSE TO EXCESSIVE HEAT. Incite DBM and Crunch Putty will quickly lose functionality if exposed to temperature above 40°C (104°F).

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 environment prior to transplant and to track expiration date accordingly.

USAGE INSTRUCTIONS

Prior to use: Examine Incite DBM Putty or Crunch Package – Do Not Use Incite DBM Putty or Crunch 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.

If for any reason the Incite DBM Putty or Crunch product is opened and not used, it should be disposed of properly or contact SPINEOLOGY Customer Service and follow appropriate return procedures. Document the reason for the non-use of the Incite DBM Putty or Crunch product and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to BONE BANK ALLOGRAFTS.

RETURNS

If for any reason Incite DBM Putty or Crunch must be returned, a return authorization is required from **SPINEOLOGY** prior to shipping. It is the responsibility of the health care institution returning Incite DBM Putty or Crunch to adequately package and label the tissue for return shipment.

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 pertinent hospital and patient medical records. 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 enclosed with each Allograft. Please attach one patient barcode label in the space provided and complete the requested information on the Transplant Record. 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

As allografts are composed of proteins such as collagen, the potential for hypersensitivity, allergic reactions or other immune responses may exist. All adverse outcomes potentially attributed to the allograft must be promptly reported to **SPINEOLOGY.**

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.

DISPOSAL

Incite DBM Putty or Crunch 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:
SPINEOLOGY Client Services at:
Phone: 651-256-8500
Fax: 651-256-8505

Spineology
anatomyconservingsurgery

7800 3rd Street North, Suite 600
St. Paul, MN 55128-5455
(888) 377-4633

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

LB-205 R00 Eff. Date: ; CN# 14.084

Spineology
anatomyconservingsurgery

PROCESSED ALLOGRAFT TISSUE PACKAGE INSERT AND RECONSTITUTION INFORMATION

READ BEFORE USING

THIS ALLOGRAFT IS DERIVED FROM VOLUNTARILY DONATED HUMAN TISSUES.

DESCRIPTION

This human tissue allograft is supplied by **SPINEOLOGY** and was processed and prepared by Texas Human Biologics (THB). All recovery, processing and distribution costs were reimbursed in part by **SPINEOLOGY** 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 guidelines of the American Association of Tissue Banks (AATB).

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). Test kits used are approved by the FDA for testing cadaveric specimens where applicable.

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

Allograft tissues are processed in a controlled 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. Final products are sized and packaged according to approved specifications and procedures and are sterilized using gamma irradiation in accordance with ISO 11137 guidelines.

Note: 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 is a normal occurrence.

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.

Do NOT refreeze product if thawed.

PACKAGING AND LABELING

Each allograft distributed by **SPINEOLOGY** is identified by its own unique serial number. The allograft is packaged in a pouch. Each pouch features a peel back seal and is also heat sealed to provide a sterile barrier. The package label includes graft details such as dimensions and/or volumes. 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**!

Allografts are supplied frozen, freeze-dried or in solution.

TRANSPORT AND STORAGE OF FROZEN GRAFTS

Frozen product is shipped frozen on dry ice via overnight courier. Upon arrival, product should be removed from the shipping container and placed in a freezer at or below -40°C (-40°F).

Alternate storage conditions (Frozen Grafts)
Product may be stored for 6 months or less from -20°C to -39°C (-4°F to -38°F).

STORAGE OF FREEZE DRIED AND SALINE PACKAGED TISSUES

Maintain allograft at room temperature (59-86°F or 15-30°C). No refrigeration necessary.

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.

Preparation Of Allograft For Use:
Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or properly discarded. Used allograft containers should be disposed of in accordance with recognized procedures for discarding medical waste material.

1. Prepare the allograft for use using the following procedures:

   a) Open the outer container to expose and remove the 1st inner peel pouch.
   b) Open the 1st inner peel pouch and deliver the innermost sterile sealed pouch containing the graft material to a sterile field.
   c) Open the sterile sealed pouch and deliver the graft to a sterile field for rehydration.
   d) If the graft is packaged in saline, utilize sterile scissors to open the fluid filled inner pouch and deliver the graft to a sterile basin.

   If for any reason the graft is opened and not used, it should be disposed of properly or contact SPINEOLOGY Customer Service and follow appropriate return procedures. 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 BONE BANK ALLOGRAFTS.

2. Rehydrate tissue using the following method:

SALINE PACKAGED TISSUES:
No further hydration required.

FREEZE DRIED TISSUES:
ALL WEIGHT BEARING ALLOGRAFTS MUST BE REHYDRATED FOR A MINIMUM OF 60 MINUTES. EXTENDED REHYDRATION TIME (UP TO 4 HOURS) IS RECOMMENDED FOR ANY TISSUE TO BE CUT, SHAPED, OR WEDGED TO REDUCE THE CHANCE OF FRACTURING.

NON-WEIGHT BEARING ALLOGRAFTS DO NOT HAVE A REHYDRATION REQUIREMENT.

1. Place the graft in a basin with sterile saline (0.9%), Lactated Ringer's, or other sterile isotonic solution for a **minimum of 60 minutes**.
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 hours** after rehydrating if the allograft is stored at room temperature. If refrigerated and stored between 2° C and 8° 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:
Note: Before use, the allograft must be thawed. The allograft must not be refrozen after thawing.

1. Thaw tissue using one of the following methods:

a) Slow Thaw Method: Approximately 24 hours prior to surgery, move the packaged allograft from freezer to refrigerator (2°C to 8° C). Do not open the package until immediately before use. When needed for surgery, follow the unwrapping procedure and proceed as described below. Refrigerated tissue must be used within 24 hours or discarded.
b) Quick Thaw Method: Follow the instructions for removing allograft from packaging. 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 40°C for rapid thawing. **DO NOT MICROWAVE THE GRAFT.**

2. Allografts must be used promptly after thawing and must not be refrozen. Allografts must be used within six hours after thawing if the allograft is stored at room temperature. If refrigerated between 2° C and 8° 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.

RETURNS

If for any reason tissue must be returned, a return authorization is required from **SPINEOLOGY** prior to shipping. **Frozen grafts are not returnable.** It is the responsibility of the health care institution returning the tissue to adequately package and label the tissue for return shipment.

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 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

As allografts are composed of proteins such as collagen, the potential for hypersensitivity, allergic reactions or other immune responses may exist. All adverse outcomes potentially attributed to the allograft must be promptly reported to **SPINEOLOGY.**

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.

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:
SPINEOLOGY Customer Service at:
Phone: 651-256-8500
Fax: 651-256-8505

Spineology
anatomyconservingsurgery

7800 3rd Street North, Suite 600
St. Paul, MN 55128-5455
(888) 377-4633

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