Exclusively foot & ankle Paragon 28®

STERILE R

BEAST™ DEMINERALIZED BONE MATRIX (DBM) PUTTY
BEAST PLUS™ DEMINERALIZED BONE MATRIX (DBM) PUTTY
PACKAGE INSERT

READ BEFORE USING

DESCRIPTION

This bone void filler was prepared from donated human tissue processed using aseptic surgical techniques. DBM Putty is a combination of human demineralized bone matrix (DBM) and a biocompatible and bioabsorbable carrier, carboxymethylcellulose, mixed into a putty-like consistency for ease of surgical use. DBM Putty is processed using either fine particles of bone or a mixture of fine particles and larger granules.

Tissue is first disinfected and then terminally sterilized in the final package using low-dose gamma radiation to provide a SAL of 10^{-6}. The material may contain traces of the processing reagents Gentamicin, PVP-Iodine, alcohol and surfactants. As a biological material, some variations in the product should be expected, such as in appearance and in handling.

OSTEOINDUCTIVITY POTENTIAL

DBM Putty is osteoconductive and has been shown to have osteoinductive potential in an athymic rat model. It is manufactured via a processing method that has been validated to consistently produce DBM that is osteoinductive in an athymic rat assay. Product and process consistency are confirmed via ongoing testing of DBM Putty finished product for osteoinductivity in a validated athymic rat assay. It is unknown how the osteoinductivity potential in the rat model correlates with human clinical performance.

DONOR SCREENING AND TESTING

The donor from whom this allograft was derived has been tested and found negative for the following:

HBsAg (Hepatitis B Surface Antigen), HBcAb (Hepatitis B Core Total Antibody), HBV-NAT (Hepatitis B Nucleic Acid Test), HCV (Hepatitis C Antibody), HIV 1/2-Ab (Antibody to Human Immunodeficiency Virus Types 1 and 2), Syphilis detection test, HIV-1 NAT (HIV-1 Nucleic Acid Test), and HCV NAT (HCV Nucleic Acid Test).

The donor was also tested for HTLV I/II (Human T lymphotrophic Virus Types I and II) and the results were found to be acceptable. Note: HTLV I/II testing is not currently a required test. If a donor was NOT tested for HTLV I/II the donor will be statused as a USA-only donor.

Additional RCDAD Donor Screening Tests Attached in this Space.

If additional donor screening tests for RCDADs are not listed in this space there were none performed.

Additional donor screening tests may have been performed on the donor. If additional tests for Human Immunodeficiency Virus, Hepatitis C or Syphilis were performed the results were reviewed and found to be **NEGATIVE**. Additional tests for other communicable diseases, such as West Nile Virus, *T. Cruzi*, Cytomegalovirus and Epstein Barr Virus may have been performed. The results of all additional communicable disease tests have been evaluated by the Medical Director and have been found acceptable according to regulations, standards and Xtant policies and procedures.

If additional screening tests were performed for relevant communicable disease agents and diseases (RCDADs) as defined by the US FDA, they will be listed along with results in the box labeled “Additional RCDAD Donor Screening Tests Attached In This Space”. Donor screening tests are performed by laboratories registered with FDA to perform donor testing using FDA-licensed tests, when available, 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.

The donor was selected based on results of the donor screening tests, review of the donor’s medical history, social history, external exam and relevant medical records available at the time of recovery which may include previous medical history, laboratory test results, autopsy and coroner reports (if performed), and information obtained from any source or records which may pertain to donor eligibility. Such records have been evaluated by Xtant’s Medical Director and are sufficient to indicate that donor eligibility criteria in place at the time of procurement have been met. This tissue is eligible for transplantation.

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 eligibility of this human tissue are on file at Xtant and are available upon request. The criteria used for donor selection are in accordance with current policies and procedures approved by Xtant. Policies and procedures for donor screening, serologic and microbiologic testing meet current standards established by the American Association of Tissue Banks and FDA Federal Regulations and Guidance Documents.

INDICATIONS AND USAGE

DBM Putty is indicated for use as a bone void filler and bone graft substitute for voids or gaps that are not intrinsic to the stability of the bony structure. DBM Putty is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone.

DBM Putty can be used as follows:

- Extremities
- Posterolateral spine
- Pelvis

A US flag on the packaging of the graft indicates the graft is only approved for distribution and use in the United States of America.

CONTRAINDICATIONS / PRECAUTIONS

The allograft should not be used if the expiration date has been surpassed, the container in which the product is stored is damaged, the product is not labeled, or the required storage conditions have not been maintained. Caution should be exercised if the patient is allergic to any of the antibiotics or chemicals listed in processing and testing. The presence of infection at the transplantation site is a contraindication for the use of this allograft.

DBM Putty is contraindicated where the device is intended for structural support in load-bearing bone and in articulating surfaces. Relative contraindications include the following:

- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease
- Pregnancy
- Hypercalcemia
- Renal impairment
- Active or latent infection
- History of, or active Pott’s disease
- Osteomyelitis or sepsis at the surgical site
- Inability to co-operate or comprehend post-operative instructions

ADVERSE EFFECTS

Possible adverse effects of using DBM Putty include, but are not limited to:

- Infection of soft tissue and/or bone (osteomyelitis)
- Fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Hypercalcemia or transient hypercalcemia
- Fracture of the newly formed bone
- Disease transmission and undesirable immune response. Extensive screening procedures have been used in the selection of tissue donors. In spite of this careful donor selection and serological testing, transmission of infectious diseases such as HIV or hepatitis could occur.

Any Transmission of Disease That Is Suspected to Be Caused by DBM Putty Or Any Other Adverse Outcome Potentially Attributed To This Graft Must Be Reported Promptly To Xtant. Any other complaints must be promptly reported to Paragon 28, Inc. at (855) 786-2828.

INSTRUCTIONS FOR USE

Caution: DBM Putty Is Provided Sterile. DO NOT RESTERILIZE.

1. DBM Putty packaging consists of the following: a) Outer Pouch (non-sterile); b) Inner Foil Pouch (sterile); and c) Sealed Jar or Capped Syringe (sterile).
2. Examine the outer pouch for integrity. Do not use if there is evidence that the outer pouch is damaged or sterility has been compromised, or if the product label or identifying bar code is severely damaged, illegible or missing. Confirm that the expiration date shown on the label has not passed.
3. Peel open the outer pouch using aseptic technique.
4. Introduce the sterile contents onto the sterile field.
5. Remove the sealed jar or capped syringe and twist off jar lid or syringe cap.
6. Remove putty or push on plunger to extrude putty for use.
7. Apply and use the DBM Putty as per established surgical technique and surgeon's preference.

Caution: This Allograft Material Is Intended For Single-Patient Use, On A Single Occasion Only. Discard Any Unused Material After The Package Has Been Opened.

Caution: Human tissue for transplantation shall not be offered, distributed or dispensed for veterinarian use.

VIRAL INACTIVATION AND CLEARANCE

The process used to make Demineralized Bone Matrix for DBM Putty was validated for its ability to inactivate and/or clear a panel of model human enveloped and non-enveloped viruses representing DNA- and RNA-containing viruses and various viral shapes and sizes. This testing demonstrated the process provides suitable viral inactivation potential for a wide spectrum of potential human viruses. This inactivation potential provides additional viral contamination risk reduction beyond that provided through donor screening.

TISSUE TRACKING

DBM Putty is packaged in sterile, single-patient-use containers and the Unique Graft Serial Number, expiration date, product code, size, and additional information are listed on the package label.

Extra labels have been included with this graft for use by the end-user.

The Hospital must maintain records so that possible infections or other adverse reactions associated with this product can be linked back to the original source. It is the responsibility of the user surgeon to complete recipient records for the purpose of tracking tissue post-transplant.

STORAGE

It is the responsibility of the Tissue Dispensing Service and/or end-user clinician or facility to maintain this product in appropriate storage conditions prior to transplantation.

DBM Putty - Store at 15°C to 30°C. Do not freeze or expose to extreme heat.

RETURNS

If for any reason tissue must be returned, please contact the Customer Service department of your distributor for return instructions.

Caution: Federal (US) Law Restricts This Device To Sale, Distribution And Use By Or On The Order Of A Physician.

Donor Eligibility Assessment and Tissue
Processed by:

Xtant Medical
664 Cruiser Lane
Belgrade, MT 59714
888-886-9354

Distributed by**:**

Paragon 28
14445 Grasslands Drive
Englewood, CO 80112
888-728-1888