Hero® DBM Putty

DEMINERALIZED BONE MATRIX (DBM) PUTTY PACKAGE INSERT

Sterilized using gamma irradiation

Read Before Using

- **This Allograft Unit is Derived from Donated Human Tissue.**
- **This Allograft is Intended for Use in One Patient, on a Single Occasion Only.**
- **Caution: Federal (USA) law restricts this tissue to sale by or on the order of a physician or hospital.**
- **Human tissue for transplantation shall not be offered, distributed or dispensed for veterinary use.**
- **This Allograft may not be Re-Sterilized.**
- **All tissue has been recovered, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB), the US FDA regulations and the Health Canada CTO Regulations and associated Standards (when applicable).**

Description

The bone void filler was prepared from donated human tissue processed using aseptic surgical techniques. These bone void fillers are 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 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.

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. It 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.

Donor Eligibility

Donor eligibility (screening and testing) is performed in accordance with US FDA regulations, AATB Standards, and Health Canada CTO regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation.
Donor eligibility determination is conducted by a licensed Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request. Donor eligibility was determined by one of the following establishments:

Xtant® Medical	AlloSource®
664 Cruiser Lane	6278 South Troy Circle
Belgrade, MT 59714	Centennial, CO 80111
(888)886-9354	(800)557-3587

The establishment responsible for donor eligibility can be identified via the donor number located on the product label. The first character, “A” or “B” corresponds to AlloSource or Xtant Medical respectively.

Donor Serological Testing

Communicable disease testing was performed by a laboratory registered with the 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. The testing was conducted using FDA licensed, approved, or cleared donor screening tests for cadaveric specimens where applicable. The records of this testing are maintained at Xtant Medical. The following required testing was performed and found to be negative or non-reactive;

- 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
- HIV-1 NAT (HIV-1 Nucleic Acid Test)
- HCV NAT (HCV Nucleic Acid Test).

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I and II (HTLV I & II) may have been performed at the time of donor screening and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed will be provided upon request.

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.

Viral Inactivation Clearance

The process used to make Demineralized Bone Matrix 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.

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 diseases
- 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
- Hypercalcemia
- 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 the graft or any other adverse outcome potentially attributed to this graft must be reported promptly to Xtant Medical

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. Complete the enclosed Transplant Utilization Record in detail and return as indicated. If the graft is not used for any reason after opening, complete the enclosed Transplant Utilization Record in detail, noting the method of disposal, and return as indicated. Copies of this information should be retained by the transplant facility for future reference.

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.

Instructions for Use

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 aspetic 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 DBM Putty or push on plunger to extrude for use.
7. Apply and use the DBM Putty as per established surgical technique and surgeon's preference.

RETURNS

If for any reason tissue must be returned, a return authorization is required from Xtant Medical prior to shipping.

Manufactured by Xtant Medical.

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

Health Canada
CTO Registration
Certificate Number
100170

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