DBM Putty
DEMINERALIZED BONE MATRIX
DONATED HUMAN TISSUE

CAUTION: DEVICE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP<71> Sterility Tests.
DBM Putty Is Not Terminally Sterilized.

DESCRIPTION
DBM Putty is processed human bone that has been demineralized and combined with sodium hyaluronate, which is a naturally derived material not of animal origin that is both biocompatible and biodegradable. The combination of demineralized bone and sodium hyaluronate results in a putty-like or textured consistency for ease and flexibility of use during surgical application.

OSTEOINDUCTIVE POTENTIAL
DBM Putty is osteoconductive, and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of final DBM Putty product is tested in an athymic mouse or in an alkaline phosphatase assay, which has been shown to have a positive correlation with the athymic mouse model, to ensure the osteoinductive potential of the final product. Standard testing performed in an athymic mouse or alkaline phosphatase assay must prove positive for the osteoinductive potential of the final product. Standard testing performed in an athymic mouse or alkaline phosphatase assay must prove positive for the osteoinductive potential of the final product.

Bone content (by weight) 4%
Sodium hyaluronate content (by weight) 6%

INDICATIONS FOR USE
DBM Putty is intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral/maxillofacial and dental intrasosous defects including:
- Filling resection defects in benign bone tumors, benign cysts or other osseous defects in the alveolar ridge wall

DBM Putty can be used with autograft or bone marrow aspirate. DBM Putty is intended for single patient use only.

CONTRAINDICATIONS
DBM Putty is NOT intended to provide structural support of the bone during the healing process. DBM Putty is also contraindicated for incomplete maxillofacial skull growth.

ADVERSE EFFECTS
Possible adverse effects of using DBM Putty include, but are not limited to:
- Potential loss of contour of maxillofacial skull
- 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

Within the United States: Adverse outcomes attributable to the tissue must be promptly reported to MTF. Outside of the United States: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.

CAUTIONS
Do not sterilize. Do not freeze. DBM Putty may extrude into facial soft tissue. Trace amounts of Gentamicin may be present. Tissue is exposed to processing solutions that may contain detergents and alcohol. Trace amounts of processing solution may remain. Caution should be exercised if the patient is allergic to any of these substances. NOTE: No β-lactam antibiotics are used during the processing of tissue in DBM Putty products. Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening and Testing). Transmission of infectious diseases may occur despite careful donor selection and laboratory testing, including serology and nucleic acid testing (NAT). Bacterial infection at the site of grafting may occur.

Closed suction or drainage is recommended to prevent fluid accumulation in the wound.

Some tissues are treated with low-dose gamma radiation. For these tissues the container label will state, “Treated with Gamma Radiation.” Samples from each donor lot of DBM Putty were tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests.

INSTRUCTIONS FOR USE
DBM Putty is packaged in a glass syringe and must be extruded into a sterile basin, not directly into the operative site. THE SYRINGE IS NOT AN APPLICATOR. Care should be taken to apply gentle, even force to the plunger when extruding DBM Putty from the syringe. Extreme force applied to the plunger may cause the glass syringe to break. NOTE: This allograft has been aseptically packaged into sterilized packaging components. To make ready for use, open the package using aseptic/sterile techniques.

1. Peel back lid of outer tray.
2. Pass inner tray to sterile field.
3. Peel back lid of inner tray.
4. Remove syringe from inner tray.
5. Remove protective cap from end of syringe.
6. Extrude DBM Putty into a sterile basin.
7. Shape and use DBM Putty as per surgeon’s preference.

DBM Putty can be used alone or mixed with autogenous bone (1:1 ratio by volume) or with bone marrow aspirate (2.0 mL/2.8 g of DBM Putty or 2.0 cc/2.8 cc of DBM Putty).
Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

DONOR SCREENING & TESTING
Prior to donation, the donor’s medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by the MTF Medical Board of Trustees.

Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA. The donor blood samples were tested for:

- Hepatitis B surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HIV-1/2 antibody
- Syphilis
- HIV-1 (NAT)
- HCV (NAT)

Additional testing of SARS-CoV-2, HTLV I & II and/or West Nile Virus (as applicable) may also have been performed. All infectious disease test results passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, consent, current donor medical history interview, physical assessment, available relevant medical records to 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 suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening, serologic and microbiologic testing, meet or exceed current standards established by the American Association of Tissue Banks.

VIRAL CLEARANCE AND INACTIVATION
A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The viral inactivation testing demonstrated suitable viral inactivation potential of the processing method for a wide spectrum of potential human viruses. The DBM Putty process further reduces the risk of viral contamination beyond donor testing and screening procedures.

PACKAGING & LABELING
DBM Putty is aseptically packaged in a sterilized syringe. The syringe containing DBM Putty is inside two sterilized plastic trays, each sealed with foil lids. The outer tray is labeled and then put in a box.

This allograft must not be used under any of the following circumstances:

- If the container seal is damaged or not intact or has any physical damage;
- If the container label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the container label has passed.

STORAGE
Store DBM Putty at ambient temperature. No refrigeration or freezing is required. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

PATIENT RECORD
Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracing tissue post-transplantation. A TissueTrace® Tracking Form and peel-off stickers have been included with each package of tissue. The serial number and the tissue description have been preprinted on the peel-off stickers. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off stickers), and comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively a system for electronic submission may be used and sent to MTF at www.mtfbiologics.org. Within the United States: Once completed, the bottom page of the form should be returned to MTF using the self-addressed mailer. Copies of this information should be retained by the transplant facility for future reference. Outside of the United States: Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained by the hospital for future reference.

Reference: Current MTF policies and procedures are in compliance with current FDA, AATB and other regulatory requirements.

Definitions of Label Symbols

For Translation of Instructions for Use

www.mtfbiologics.org

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician or dentist.

MTF tissue forms and products are protected by one or more issued or licensed United States patents. A list of patents on available tissues and related technologies may be found on the MTF web site www.mtf.org/patients. MTF Musculoskeletal Transplant Foundation and TissueTrace are registered trademarks of the Musculoskeletal Transplant Foundation, Edison, NJ USA. ©2022 Musculoskeletal Transplant Foundation.