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READ BEFORE USING

Legacy™ Demineralized Bone Matrix

DONATED HUMAN TISSUE

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

THIS TISSUE WAS RECOVERED FROM A DECEASED DONOR FROM WHOM LEGAL AUTHORIZATION OR CONSENT HAS BEEN OBTAINED. THIS RECOVERY WAS PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.

DESCRIPTION AND INDICATIONS FOR USE

Legacy™ Demineralized Bone Matrix 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 -like consistency for ease and flexibility of use during surgical application.

Legacy DBM is intended for use as a Demineralized Bone Matrix for voids or gaps that are not intrinsic to the stability of the bony structure. Legacy DBM is indicated for treatment of surgically created osseous defects or osseous defects created from traumatic injury.
Legacy DBM can be used as follows:

- Extremities
- Posterolateral spine
- Pelvis
- Ridge augmentation
- Filling of extraction sites
- Cranium
- Craniofacial augmentation
- Mandibular reconstruction
- Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture
- Filling resection defects in benign cysts, or other osseous defects in the alveolar ridge wall
- Filling of cystic defect
- Filling of lesions or periodontal origin
- Filling of defects of endodontic origin

Legacy DBM can be used as an extender in the spine, pelvis, and extremities with autograft or allograft. Legacy DBM can be used with bone marrow aspirate. Legacy DBM is for single patient use only.

OSTEOINDUCTIVE POTENTIAL

Legacy DBM is osteoconductive and has been shown to have osteoinductive potential in an athymic mouse model. Every lot of Legacy DBM product is tested *in vivo* or in vitro, 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 vivo* or in vitro must prove positive for lot release. It is unknown how the osteoinductive potential measured *in vivo* or in vitro, will correlate with clinical performance in human subjects.

CONTRAINDICATIONS

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

CAUTIONS AND WARNINGS FOR USE

Do not sterilize. Do not freeze. Legacy DBM may extrude into facial soft tissue and the effect of extrusion in cranial applications, due to the lack of soft tissue, has not been investigated.

Trace amounts of Gentamicin may be present. Tissue is exposed to processing solutions that may contain detergents and alcohol. Trace amounts of processing solutions 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 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.

Use caution in the following circumstances:

- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Pregnancy
- Hypercalcemia
- Renal-compromised patients
- History of or active Pott's disease
- Osteomyelitis at the surgical site
- Sepsis in or around the surgical site
- Inability to cooperate with and/or comprehend post-operative instructions

ADVERSE EFFECTS

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

- Potential loss of contour of 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.**

DEVICE INFORMATION

Legacy DBM is composed of Demineralized Bone Matrix and sodium hyaluronate. The demineralized bone allograft in this product is prepared from tissue procured from a deceased donor using aseptic surgical techniques. The bone used in Legacy DBM is cortical bone. These tissues were treated with Gentamicin and were cleaned using 70% ethanol and washed with purified water. The bone was demineralized using hydrochloric acid. The demineralized bone was then lyophilized to a controlled moisture content. The demineralized bone was combined with sterile-filtered sodium hyaluronate prior to packaging.

Sodium hyaluronate is a naturally derived material that is biocompatible and biodegradable. The sodium hyaluronate is mixed in a phosphate buffered saline and is added to the demineralized bone to aid in maintaining physiological pH as well to improve the handling characteristics of demineralized bone.

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 Legacy DBM were tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests.

INSTRUCTIONS FOR USE

Legacy DBM 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 Legacy DBM from the syringe. Extreme force applied to the plunger may cause the glass syringe to break.

Legacy DBM can be used alone or mixed with autogenous or allograft bone (1:1 ratio by volume), or with bone marrow aspirate (2.0 mL/2.8 g of Legacy DBM or 2.0 cc/2.8 cc of Legacy DBM).

NOTE: This allograft has been aseptically packaged into sterilized packaging components. To make ready for use, open the package using aseptic/sterile techniques.

Instructions for Opening the Packaging:

1. Peel back the lid of the outer tray starting at one of the corners and peel open in a continuous motion.
2. Pass inner tray to sterile field.
3. Peel back lid of inner tray in a continuous motion.
4. Remove syringe from inner tray.
5. Remove protective cap from end of syringe.
6. Extrude Legacy DBM into a sterile basin.
7. Shape and use Legacy DBM as per surgeon's preference.

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.

STORAGE

Store Legacy DBM 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.

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 tissue 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 virus (HBV) surface antigen
- HBV core antibody
- Hepatitis C virus (HCV) antibody
- HIV-1/2 antibody
- Syphilis
- HIV-1 NAT
- HCV NAT
- HBV 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, authorization, 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 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 Legacy DBM process further reduces the risk of viral contamination beyond donor testing and screening procedures.

PACKAGING & LABELING

Legacy DBM is aseptically packaged in a sterilized syringe. The syringe containing Legacy DBM is inside two 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.

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. Please record the patient ID, name and address of the transplant facility, allograft tissue information (using the peel-off stickers), and comment regarding the use of the tissue on the TissueTrace Tracking Form. Alternately, a system for electronic submission may be used and sent to MTFTTC@Sceris.com. ***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.

Note: Not all tissue forms are available for International distribution.

DEFINITIONS OF LABEL SYMBOLS

Consult instructions for use

Do Not Reuse

For Translation of Instructions for Use

www.mtfbiologics.org

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