

READ BEFORE USING

DBX® Demineralized Bone Matrix Paste & Mix

DONATED HUMAN TISSUE

CAUTION: DEVICE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
DBX Paste and DBX Mix Are 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

DBX Demineralized Bone Matrix Paste and DBX Demineralized Bone Matrix Mix are 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 paste-like or textured consistency (DBX Paste and DBX Mix, respectively) for ease and flexibility of use during surgical application.

OSTEOINDUCTIVE POTENTIAL

DBX Paste and DBX Mix are osteoconductive and have been shown to have osteoinductive potential in an athymic mouse model. Every lot of final DBX Paste and DBX Mix product is tested *in vivo* for osteoinductive potential. Standard testing performed in an athymic mouse model must prove positive for lot release. It is unknown how the osteoinductive potential, measured in the athymic mouse model, will correlate with clinical performance in human subjects.

INDICATIONS FOR USE

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

DBX Paste and DBX Mix can be used with bone marrow aspirate. DBX Paste and DBX Mix are for single patient use only.

Indications for Use	DBX Paste	DBX Mix
Extremities	√	√
Spine		√
Pelvis	√	√
Ridge augmentation	√	
Filling of extraction sites	√	
Craniofacial augmentation	√	
Mandibular reconstruction	√	√
Repair of traumatic defects of the alveolar ridge, excluding maxillary and mandibular fracture	√	
Filling resection defects in benign tumors, benign cysts, or other osseous defects in the alveolar ridge wall	√	
Filling of cystic defect	√	
Filling of lesions of periodontal origin	√	
Filling of defects of endodontic origin	√	

CONTRAINDICATIONS

DBX Paste and DBX Mix are NOT intended to provide structural support of the bone during the healing process. DBX Paste and DBX Mix are also contraindicated for incomplete skull growth.

ADVERSE EFFECTS

Possible adverse effects of using DBX Paste and DBX Mix 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

***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. 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 DBX Paste and DBX Mix 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 such as HIV or hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of careful donor selection and serological testing.

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

DEVICE INFORMATION

DBX Paste and DBX Mix are 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 the DBX Paste is cortical bone; DBX Mix is composed of 80% cortical bone and 20% cancellous bone. These tissues were treated with Gentamicin and were cleaned using 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.

	DBX Paste	DBX Mix
Bone Particle Diameter	212 – 850 μ m	\leq 6mm
Sodium hyaluronate content (by weight in solution)	2%	4%
Bone content (by weight)	26%	35%

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

INSTRUCTIONS FOR USE

DBX Paste 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 DBX Paste from the syringe. Extreme force applied to the plunger may cause the glass syringe to break. DBX Mix is packaged in a glass jar. Use the enclosed sterile spatula to remove DBX Mix from the jar. **THE SPATULA IS NOT AN APPLICATOR.**

DBX Paste and DBX Mix can be used with bone marrow aspirate.

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:

DBX Paste	DBX Mix
1. Peel back lid of outer tray.	1. Peel back foil lid of tray.
2. Pass inner tray to sterile field.	2. Aseptically present the tray to the scrub nurse.
3. Peel back lid of inner tray.	3. The scrub nurse will first retrieve the plastic retainer and the plastic spatula on top.
4. Remove syringe from inner tray.	4. The scrub nurse will secondly remove the glass jar underneath the plastic retainer. CAUTION: Retainer is not intended for holding the glass jar.
5. Remove protective cap from end of syringe.	5. Remove lid from jar.
6. Extrude DBX Paste into a sterile basin.	6. Use spatula to remove DBX Mix.
7. Shape and use DBX Paste as per surgeon's preference.	7. Shape and use DBX Mix 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.

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
- HBV (NAT)
- HIV-1/2 antibody
- Syphilis
- HIV -1 (NAT)
- HCV (NAT)

All infectious disease tests were negative. 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 DBX Paste and DBX Mix process further reduces the risk of viral contamination beyond donor testing and screening procedures.

PACKAGING & LABELING

DBX Paste is aseptically packaged in a sterilized syringe. The syringe containing DBX Paste is inside two sterilized plastic trays, each sealed with foil lids. The outer tray is labeled and then put in a box.

DBX Mix is aseptically packaged in a sterilized glass jar which is then packaged inside a plastic tray with a foil lid. The tray is then labeled and put into 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 DBX Paste and DBX Mix 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 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.

Definitions of Label Symbols



See IFU



Do Not Reuse

Processed by:



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Within the United States: 1.800.433.6576
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All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

CAUTION: Federal (US) law restricts this device to sale, distribution and use by or on the order of a physician. Please note: Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.

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.

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